UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	**MD-15-02641-PHX-DGC**
	Phoenix, Arizona
	May 22, 2018
Doris Jones, an individual,	
Plaintiff,	
v.	CV-16-00782-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 5 - A.M. SESSION

(Pages 935 - 1076)

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08:30:08 **P R O C E E D I N G S**

(Proceedings resumed in open court outside the presence of the jury.)

08:30:37 THE COURT: Thank you. Please be seated.

Good morning, everybody.

EVERYBODY: Morning.

THE COURT: As you saw, I issued an order on Saturday dealing with the Rule 1006 chart. I'll let you all look that
08:30:57 over. And when you have a chance, on the defense side, review it. If there's issues I need to address, I'll be happy to. Otherwise, you can just apprise me as to when you want to put it in evidence.

I looked as well at the FDA warning letter issue,
08:31:17 which I think is Exhibit 1680. I want to wait to rule on the admissibility of that. In the Booker trial it was on the morning of Day 9 that I ruled, when I had seen enough of the evidence to know its relevancy.

I want to hold off and see how the evidence comes in
08:31:35 as well, consistent with the ruling I made on a motion in limine before the Booker trial. So that's what we'll do on the FDA warning letter.

But feel free to raise it if you think at a particular point it becomes relevant. Otherwise I'll just
08:31:50 plan to hold it for a few more days and see how the evidence

08:31:53 comes in and then rule on whether it's admissible. Well, whether Section 3 is admissible. That's all plaintiff has moved into evidence.

A couple of other matters I wanted to mention.

08:32:10 There was testimony late in the day on Friday where a witness, and I'm not even remembering who it was, made reference to other cases against Bard. I think everybody should be advising their witnesses not to discuss other cases, consistent with the ruling that I made before the trial.

08:32:31 And when you put an expert witness on, please provide me with a copy of the report so that we can deal with objections of nondisclosure quickly. I'd prefer to even avoid a sidebar. If there's a nondisclosure objection, I think I'll just ask the questioning lawyer tell me where it is in the

08:32:50 report. And if I can't find it, we'll do a sidebar. But that way we can move through those issues quickly.

MR. COMBS: Your Honor, can I make a point on that?

THE COURT: Yeah.

MR. COMBS: The plaintiffs are going to call

08:33:01 Dr. Hurst after we finish the Hudnall deposition. What I have is his report, his -- there were two transcripts from his deposition because it was continued, and also the transcript of his Booker testimony.

Can I approach and give these to you now? And what I

08:33:24 would say is that I'd just refer to the Booker -- transcripts

08:33:28 1 1, 2, and 3.
2 THE COURT: That's fine.
3 MR. ROGERS: One brief on that. I know that
4 Mr. Combs said he'd refer to them as Booker 1, 2, and 3 --
08:33:46 5 MR. COMBS: No, no.
6 THE COURT: I think he said transcript 1, 2, and 3.
7 MR. ROGERS: I apologize. I misheard.
8 MR. COMBS: Yeah, whatever they are.
9 And then, we believe, Your Honor, and obviously we
08:33:57 10 had quite a bit of sidebar --
11 THE COURT: Is this the same issue?
12 MR. COMBS: Yes, correct.
13 THE COURT: Okay.
14 MR. COMBS: With Dr. Muehrcke, we want to avoid that
08:34:05 15 as well. We do think the Court was overly restrictive on what
16 he could say or couldn't say as far as not being specifically
17 mentioned in his report. I have some legal authority. We
18 pulled -- I don't know if you want me to give it to you now
19 or -- at some point if it becomes an issue, I would like to
08:34:22 20 make a record on it.
21 THE COURT: You can make a record. I'll tell you
22 what I am relying on. I'm relying on the fact that in my case
23 management order I said that the reports had to include a full
24 and complete disclosure of everything that would be said
08:34:34 25 during trial, and I specifically cited to the advisory

committee note to Rule 26(a)(2)(B) which says that a report should set forth everything a witness is going to say on direct testimony. That's been the standard I've been applying to expert witnesses for 15 years. And I try to be real clear in my case management order that's what's required. I know there are other courts that are more liberal. I don't agree with them. I don't think that is the intent of 26(a)(2)(B)

So that's the basis upon which I'm holding parties to what is actually in the report, and I tried to make that real clear in the case management order in this case.

MR. COMBS: Understood, Your Honor.

THE COURT: But, yeah, absolutely. If you think I'm getting it wrong and you want to make a record, you can certainly do that at the appropriate time.

MR. COMBS: Thank you, Your Honor.

THE COURT: The other thing I wanted to mention is I have been resisting the temptation to ask a questioning lawyer if he wants to display something to the jury. And as a result there's been folks coming up and telling the lawyer, which is fine. I finally couldn't resist the temptation when one of the defense lawyers was up, because the jury was just trying to follow what was going on and they couldn't because it wasn't in front of them.

I'm going to try not to prompt you on that. So please remember to ask the jury -- I mean, to ask me to

display it.

I think I need to be fair to both sides. I haven't prompted plaintiff yet, but I just felt I had to with one defense lawyer on Friday because the jury looked lost trying to follow what was being said. So please remember to do that.

All right. Are there matters that plaintiff's counsel wants to raise before we get started this morning?

MR. CLARK: There are, Your Honor.

I think they will be brief. We have -- we plan to rest tomorrow. One of the things that concerns us is wanting to make sure that we have adequately made a record that we've offered the 1006 summary, the monthly management reports that we dealt with with Mr. Modra, as well as some of the redacted issues that need to be substituted.

So I have spoken with counsel for Bard and we agree that we can rest subject to whatever ruling the Court makes on those and obviously substituting redacted exhibits. But I just wanted to be comfortable that the Court was okay with that, that we don't waive our right to seek admissibility of those in our case after we've rested. I think we have actually asked for those to be admitted but we are abiding the Court's ruling with respect to the monthly management reports, and then obviously we need to comply with what you've ordered on Saturday on the 1006 summary. And that may take some back and forth time.

08:37:29 THE COURT: On Saturday I said, "After considering the parties Rule 403 arguments, the Court will admit the Complaint Record Detail Reports and the monthly management reports identified during the testimony of Mr. Modra."

08:37:45 MR. CLARK: That solves that problem. Thank you.

THE COURT: Yeah. Now, with the redactions that Mr. North raised about his name. But after you work out those redactions, I'm admitting those. I think we need to do it in front of the jury again. And I didn't go back on Saturday and

08:37:59 try to get those exhibit numbers. So -- but it's the ones, I think there were two of each, that were covered with Mr. Modra. My view is those are admissible.

MR. CLARK: Okay. And to the extent we don't yet have the redactions done, can we do that in the defendants'

08:38:15 case without prejudice to having offered it and sought admission of it in our case?

THE COURT: Yeah, that sounds fine to me.

Do the defense attorneys have any objection to that?

MR. NORTH: None, Your Honor.

08:38:24 THE COURT: Yeah, that's fine.

MR. CLARK: And the same would be true with respect to the 1006 summary that we need to prepare?

THE COURT: Right.

MR. O'CONNOR: Hey, Shannon.

08:38:33 (Counsel confer.)

08:38:35 MR. CLARK: And I apologize, Your Honor. My attorneys have advised that there is an issue. I think the Court's -- our understanding was that we could present up to, I think, ten reports, and it may not be that ten of them have
08:38:54 been presented with Mr. Modra. So whatever --

THE COURT: Well, no, I didn't say you could admit ten reports. What I said was that we would admit the reports that you moved into evidence during Mr. Modra, and then in the Rule 1006 exhibit you can provide ten exemplars from each of
08:39:11 the four categories of fillers, which includes the event description from Bard. My intent was not that the reports underlying all of those would come in. Nobody had raised that before.

MR. O'CONNOR: I think we're talking about two
08:39:26 things.

THE COURT: Okay.

MR. O'CONNOR: Understood your ruling about the complaint files, but there's also those monthly management reports.

08:39:35 THE COURT: You only covered two of those with Mr. Modra; right?

MR. O'CONNOR: For the same reason that I was giving examples, but I think in his actual testimony there were two, that's correct.

08:39:45 THE COURT: So are you saying you want more of those

admitted?

MR. O'CONNOR: Well, that was our plan.

THE COURT: Okay. I didn't know that. I wasn't aware that that was something you wanted to do.

MR. O'CONNOR: Well, we have the two in. Can we revisit and show you the ones we wanted based upon the foundation?

THE COURT: Yeah. I mean, you talk to defendants about that.

Here's the issue that I'm not clear on, Mr. O'Connor. My memory is that those monthly management reports have pages at the end of complaints, and if we put ten of those in and there's 15 or 20 complaints at the back of each one, we're putting in 150 or 200 different specific details about complaints.

And my thought on the 1006 ruling was we'll give the jury a good exemplar of what's in there, but we're not going to put in scores or hundreds of them. And it seems to me we do that, in effect, if we put in ten monthly management reports.

MR. O'CONNOR: All right. I understand your position.

(Counsel confer.)

MR. STOLLER: Your Honor, let me address that real quickly.

08:40:56 The part of the reason we look at the monthly management reports is, one, there's some content in the body of it before that. And so in some cases we want to talk about that content, which is the nonreporting of the adverse events.

08:41:09 But the other thing about the adverse event part in those monthly management reports is we're focused not on a long stretch of time. The ones we're looking at are immediately surrounding the implantation of Mrs. Jones, where there's particular importance, we think, in what Bard knew at

08:41:28 that time that was happening with respect to these particular filters shortly after the Eclipse has come to market because, if you'll recall, I believe it came to market in June -- excuse me, January of 2010, and she's implanted later that year, and shortly after implantation.

08:41:43 So it's not an attempt to get around the order you've given on the broader pool of adverse events, but it is specific as to time in what they knew at that time and what warnings were given at that time in light of the events that were happening leading up to and immediately following her

08:42:00 implantation. So it has a specific temporal component to it that is not captured by the ruling you've given on the overall adverse events.

THE COURT: I think this is the first time I've ever heard about this. I don't think you've moved in ten monthly

08:42:17 management reports or --

08:42:20 MR. STOLLER: I don't believe we have, Your Honor.

THE COURT: -- or made this argument about clustering them around Ms. Jones' implant. So I haven't thought about that. I haven't looked at them. I don't know what exhibits
08:42:30 you're talking about. I don't know the defendants' reaction.

I think if you want to do that, what you ought to do is identify them, for me and for the defendants. I'll be happy to hear what the defendants have to say. Then I can look at them. But this specific issue I don't think I've
08:42:47 heard before.

MR. O'CONNOR: Just one point. So, Your Honor, I understand what you're saying. I think we can bring that to your attention, and I think you understood that one purpose that I was serving with Mr. Modra was just to lay foundation
08:43:03 for the types of reports.

And so based upon that, I think we would like to at least move in these additional temporal reports based upon his foundation that we already laid.

THE COURT: Okay. Yeah. Well, let's identify them
08:43:16 and I'll be happy to consider them --

MR. O'CONNOR: Thank you.

THE COURT: -- and hear objections from the defendants.

MR. O'CONNOR: All right. Thank you.

08:43:23 THE COURT: Okay.

08:43:28 MR. CLARK: One issue pertains to a video deposition that we anticipate playing after the first witness, the first live witness, I should say. We realized a day or two ago that one of the important designations that was initially 08:43:40 designated internally and at some point did not make it into the submission to the Court, fell on the cutting room floor or somehow was not placed in there, so we would seek to leave to add that to the deposition testimony of Dr. Avino.

And for the record, it is lines 89/14 through 89/22 08:44:00 and lines 90 -- page 90, line 20 -- sorry, page 90, line 12 through 22.

THE COURT: Have you talked to defense counsel about this?

MR. CLARK: I have. And there is a 401, 403 08:44:16 objection to them. If I could be permitted to read the testimony to the Court --

THE COURT: When is this likely to come up?

MR. CLARK: With our first deposition witness, after Dr. Hurst, who will be the first live witness.

08:44:27 THE COURT: When is that likely to happen?

MR. CLARK: Depending on how long Dr. Hurst takes, I think it could be around 10:00, 10:15, something like that.

THE COURT: Okay.

MR. CLARK: So the testimony to Dr. Avino is:

08:44:39 "Question: The fracture rates they're reporting

08:44:43 here aren't vague. True?"

"Answer: Correct. You're right."

"Question: And is that information that would have been important for you in deciding to use Bard

08:44:51 IVC filters?"

"Answer: Yes. All of the fracture information rate is something that was important to consider in this decision."

"Question: Is that information that would have

08:45:02 been important to you to know, that the medical director for Bard in 2005 was questioning why Bard was pushing the G2 as a permanent filter when they already had the SNF one?"

"Answer: Again, all information is helpful if

08:45:19 it's information regarding concern about one filter being better than the other."

So, Your Honor, I think particularly given the causation defense that is being challenged in this case, that is important testimony to talk about the comparative rates and

08:45:34 questions about other -- the Simon Nitinol and the G2. So we don't think it is prejudicial really at all because it's just testimony about that. Somehow or another there was an error that this did not get submitted. But I do think that's harmless error under the circumstances. But that would be our

08:45:54 record on that. We think it is important testimony for the

causation defense.

THE COURT: All right.

MS. HELM: Your Honor, again, this was not submitted to the Court to review when you reviewed the deposition in its full context, and the testimony is about a -- he's being questioned about a line in an e-mail, and he's not given the full context of the e-mail. And I think the prejudice of him asking a doctor to react on one line in an e-mail rather than in the whole context outweighs any probative value.

There are other places in that -- sorry. There are other places in the deposition where the doctor talks about wanting to know as much information as possible and what information would be important to him.

So I think this line taken out of context in this scenario is -- the prejudice of it outweighs any relevance, especially in the context of the whole deposition where they have that information previously as it relates to other Bard documents.

THE COURT: Well, let me ask you a question on that, Ms. Helm. I assume the line in the e-mail is the one we've seen a number of times that was by -- was it Dr. Ciavarella or -- where he's asking if we've got the SNF that has virtually no complaint history, why are doctors choosing the Recovery filter as a permanent filter when we have this alternative.

08:47:23 That's not the wording, but that was the essence --

MS. HELM: It's actually the G2, Your Honor, and that's really close.

THE COURT: Yeah. I remember the line. And as I 08:47:33 understand the question that was asked to Dr. Avino, it was, would you have wanted to know that the medical director or a manager within Bard was asking this question in light of fracture rates.

What is the unfair prejudice?

08:47:53 MS. HELM: Actually, Your Honor, the question was not wouldn't you have wanted to know that the medical director was questioning this, the question is, wouldn't it have been important to know that the medical director was questioning why Bard was pushing the G2 as a permanent filter when it 08:48:11 already had the SNF one.

So I think the way the question's asked, it raises a prejudicial effect and it takes the statement out of context. We don't have the e-mail. They haven't marked it as an exhibit. So I think that that -- just in the context, 08:48:27 particularly in light of the entire deposition where they have other questions of Dr. Avino, would you want to know questions.

And I may be wrong about the exhibit, I'm sorry, it's not marked.

08:48:39 THE COURT: I think you're saying in the deposition.

But it's already admitted in the trial; right?

MS. HELM: Yes, Your Honor, it has.

THE COURT: It's in evidence.

MS. HELM: Yes, Your Honor.

THE COURT: So is your objection that the question misstates what the e-mail says?

MS. HELM: Yes, Your Honor.

THE COURT: Do you have the e-mail, Mr. Clark?

MR. CLARK: The e-mail is in evidence. It's Exhibit 991. I don't have it with me right now.

I believe the witness was questioned with the e-mail right? So we didn't cut the part that talked about that because it is already in evidence. But --

THE COURT: Do you have the transcript?

MR. CLARK: I do. I can -- may I approach?

THE COURT: Yeah.

Well, what you've given me, Mr. Clark, is not the transcript, it's the excerpts.

MR. CLARK: I apologize. I do not have the transcript with me. I can -- the transcript should be up here, if I can grab that.

THE COURT: Yeah. I think I just need to see the context in which the question is asked.

MR. CLARK: May I approach --

THE COURT: Yeah.

08:50:38 While he's looking for that, are there other matters the plaintiff's counsel need to raise this morning?

MR. O'CONNOR: No, I don't think so, Your Honor.

THE COURT: How about from defense counsel?

08:50:48 MR. LOPEZ: Hold it. We do have one more thing, Your Honor.

As you recall, when we played Dr. Altonaga --

THE COURT: I thought you were bringing your phone up to hand it in this morning.

08:50:57 MR. LOPEZ: That's why I have it out. I'm looking for Nancy.

You threw me off, Judge.

When Dr. Altonaga's video deposition was played in Booker, there's a part in there and, if you'll recall, I asked

08:51:11 you if I could read it. Because the court reporter reads it to the witness, you cannot hear it. And I'm wondering if we can -- if I could read that section of Altonaga's dep- -- it is important testimony, and there's no way the jurors heard it.

08:51:28 THE COURT: When is this?

MR. LOPEZ: It already happened. I mean, Dr. Altonaga's video deposition has already been played and, unfortunately, I was sitting in the back of the room without the run and forgot about the section until it actually played.

08:51:42 THE COURT: What is the section?

08:51:47 MR. LOPEZ: The question is: "Would it be your expectation when Bard launched the filter for commercial use that Bard would have an awareness about the long-term clinical performance of that device?"

08:51:57 The answer was "Yes."

But that was a reread by the court reporter that you just -- there's no way could you hear.

THE COURT: Okay. Read it to me one more time.

MR. LOPEZ: Question: "Would it be your expectation 08:52:32 that when Bard launched a filter for commercial use that Bard would have an awareness about the long-term clinical performance of that device?"

"Answer: Yes."

You could hear the yes, but you could not hear the 08:52:46 question.

THE COURT: What I have in my notes, having just listened to what he testified to, is that he said it was prudent for a company to understand how its device performs.

Isn't that essentially the point?

08:53:01 MR. LOPEZ: Yeah. But, I mean, it was played, Your Honor. This testimony was actually played in the video.

THE COURT: I know. My point is I got that from the video. I wasn't following along in a transcript.

MR. LOPEZ: Okay.

08:53:09 THE COURT: Do you think the jury missed it?

08:53:11 MR. LOPEZ: Well, I mean, this is a little different. I mean, I -- not prudent. It would be his expectation.

THE COURT: And so what you're proposing to do is just read the question and answer?

08:53:24 MR. LOPEZ: Yes, sir.

THE COURT: Mr. North?

MR. NORTH: Well, on that, I just think it reemphasizes the testimony. I think it was clear the first time.

08:53:33 THE COURT: Do you think it could be heard by the jury?

MR. NORTH: I thought it could.

THE COURT: It was faint. I remember it being faint.

My only concern, Mr. Lopez, is whether we're

08:53:46 reemphasizing any particular evidence. I don't think that's a big risk here. So what I will allow you to do is just I'll point out there was a point in the transcript that was faint. We're not trying to emphasize this evidence, but just to make sure the jury heard it we'll let you read it.

08:54:03 MR. LOPEZ: All right. Thank you, Your Honor.

THE COURT: Okay.

MR. CLARK: May I approach with the iPad version of the transcript? I can't find it quickly in boxes.

THE COURT: Yeah, that's fine.

08:54:25 So is 4026 in the deposition -- the exhibit we're

08:54:30 talking about, the e-mail?

MR. CLARK: It is, Your Honor. It's Trial Exhibit 991.

And if I could hand that to the clerk?

08:54:37 THE COURT: Yeah, that would be fine.

I'm going to overrule the objection. I think this is relevant and not unduly prejudicial. Unfairly prejudicial. So I will allow that to be added to the video that's going to be shown.

08:55:55 MR. CLARK: Thank you, Your Honor.

We have one more issue with a deposition, but I think that deposition will be an afternoon deposition, so we can --

THE COURT: Let's not talk about it now because we've only got three minutes left. I want to hear defendants' issues.

08:56:05 MR. NORTH: Your Honor, with all due respect to the plaintiff's counsel, we are concerned about a recurring event in this trial, and that's that they monopolize with all their issues the 30 minutes we have.

08:56:14 We have two very important issues. One doesn't need to be decided right now, but the other one does need to be decided before the plaintiff testifies, and our understanding is they're putting her on this morning. And Ms. Helm has that issue, but I don't know that we can get it done before 9:00.

08:56:30 THE COURT: What's the issue?

08:56:36 MS. HELM: Your Honor, on the first day of trial you instructed us not to raise the issue of the plaintiff's smoking without first approaching the Court. So I'm approaching the Court on the issue of her smoking and on her
08:56:49 other medical conditions, based on two events that have occurred since you gave us the instruction.

I don't think I can argue this in three minutes, Your Honor. I have testimony, I have case law, I have quite a bit. But the issue relates to we believe the door has been
08:57:06 opened to her smoking and also to all of her medical conditions and comorbidities based on the testimony of Dr. Muehrcke on Friday, and also on based statements by counsel in the opening statement.

THE COURT: Well, let me ask plaintiff's counsel,
08:57:25 when are you going to put on Ms. Jones?

MR. O'CONNOR: Prior -- later, probably, in the morning after the break.

THE COURT: And how long will your direct of her take?

08:57:33 MR. O'CONNOR: About 20 minutes.

MS. HELM: How long?

MR. O'CONNOR: Her direct? 20 minutes.

THE COURT: Okay.

MR. O'CONNOR: I mean, it's -- hopefully.

08:57:44 THE COURT: How long will your cross take?

08:57:46 MS. HELM: Your Honor, it depends on your ruling on this issue.

THE COURT: Well, without this, how long will it take?

08:57:52 MS. HELM: Probably 15 or 20 minutes.

THE COURT: Okay. Well --

MS. HELM: Your Honor, this also frankly impacts the cross-examination of Dr. Hurst because if you allow this issue in, it impacts what Mr. Rogers can ask Dr. Hurst on

08:58:10 cross-examination.

THE COURT: All right. Tell me what it is you think you should be allowed to do.

Traci, would you tell the jury we're going to be a few minutes.

08:58:24 MS. HELM: Thank you, Your Honor.

On Friday Dr. Muehrcke testified that the plaintiff is, quote, a breath away from having a serious problem, a death.

It's on page 776 --

08:58:32 THE COURT: I remember that testimony.

MS. HELM: Okay. We should be able to introduce evidence that disputes Dr. Muehrcke's opinion as to causation. This does not go to contributory negligence, but it goes to whether there are other possible causes for her being a breath

08:58:52 away from having a serious problem. She suffers from a number

08:58:55 of serious medical issues that both predated and postdated the retrieval of the filter.

The plaintiffs have changed course through the case, throughout the entire case. There were physical symptoms that 08:59:11 they attributed to the filter strut, and as you will recall on the first day of trial, they started withdrawing those. But those physical symptoms all are preexisting, all relate to a very complicated medical history.

She's had four very complicated GI bleed surgeries, 08:59:31 including one that postdates the retrieval of the filter and put her in the ICU, was emergent. She suffers from anemia, chronic hypertension, peptic ulcer disease, repeat GI bleeding, hypothyroidism, and migraine headaches. All of this history is now clearly relevant to what Dr. Muehrcke said. 08:59:53 The jury is entitled to consider whether there are other causes of her being a breath away from a serious problem, including her smoking.

Your Honor, in *Wages* -- and I have these cases for the Court to consider -- in *Wages versus S-I-B-R-A-N*, at 171 09:00:14 Georgia Appeal 14, the Georgia Court of Appeals held that: A plaintiff's other injuries or medical conditions are admissible to show that the injuries at issue are not the result of the defendant's negligence and that they can come in through a cross-examination of the plaintiff.

09:00:33 Likewise, in *Lindsay versus Turner*, 279 Georgia

09:00:38 Appeal 595, the plaintiff argued that the defendant should not have been permitted to testify -- to question him about, quote, wholly unrelated, close quote, conditions allegedly incurred prior to and after the accident.

09:00:55 But the Court held that evidence concerning a plaintiff's other medical conditions may be admissible to show that the issue -- the injuries currently at issue are not the result of the defendant's negligence.

And I understand that Dr. Muehrcke was testifying as 09:01:10 to the retained strut in her pulmonary artery, but what this jury heard is she's a breath away from serious injury or death. The jury's entitled to know whether there are other causes for her being a breath away from serious injury or death. And they're entitled to know that this complicated 09:01:31 medical history that is continuing into today, that her smoking, which the Court has already found is common knowledge and contributes to her medical condition, it's well-known, the jury's entitled to consider that.

And what the plaintiffs are trying to do here is 09:01:50 they're trying to paint a picture that Ms. Jones was perfectly healthy after the strut was -- except for the retained strut, and that there were no other comorbidities that could put her in a hospital or cause a serious medical condition. And that is simply not the case.

09:02:06 And under Georgia law, her other comorbidities, her

09:02:09 other medical conditions, her other causes of potentially being a breath away, should be heard by the jury and considered by the jury in making the determination of causation.

09:02:23 Also, in opening statement, Mr. O'Connor, and I quit counting, but it was more than five times said she has pain and suffering. He didn't just say mental pain and suffering, he continually said pain and suffering.

In the pretrial order, the plaintiff makes a claim 09:02:42 for physical pain and suffering past, present, and future.

They've asked for a jury charge on physical pain and suffering and mental pain and suffering.

To the extent that Ms. Jones and her family members are going to come in here and say anything about pain and 09:03:01 suffering, the jury's entitled to know other causes of that pain and suffering.

And, frankly, Your Honor, it goes to her worry. She's going to come in and say she's worried about the strut. Dr. Muehrcke went on and on and on about this worry of the 09:03:17 strut, she's a breath away.

We should be entitled to cross-examine her about whether she's worried about her hypertension, whether she's worried about her anemia, whether she's worried about her hypothyroidism, whether she's worried about the impact that 09:03:31 the smoking has on her health.

09:03:33 She's going to come in and testify and her daughter's going to come in and testify that they worry something's going to happen with her grandchildren.

And, actually, if you look at her medical history, 09:03:43 every time she's had an emergent medical situation it has been unrelated to the filter, except for potentially 2015. But since then she's had to go by ambulance to the hospital. So this worry and this worry that something could happen when she has her grandchildren, the jury should also be able to 09:04:02 consider that there are other causes for that worry and that -- and those conditions.

And so, pursuant to your order, we're raising this issue. We believe that it's completely prejudicial to the defendant and unfair and inappropriate under Georgia law to 09:04:17 allow the plaintiffs to come in and try this case as she got a filter, the filter broke, there's a retained strut, and that's all that matters, because she has a number of comorbidities that her expert should have been aware of, and that we should be able to both cross-examine her and the other fact witnesses 09:04:36 about.

And I have copies of case law if you'd like it, Your Honor.

THE COURT: No. We don't need it. Thank you. We can find those cases.

09:04:43 Plaintiff's response?

09:04:50 MR. COMBS: Your Honor, the Court's been very strict in this case about its rulings on -- not deciding this case on irrelevant things that might be unfairly prejudicial. Obviously, the plaintiffs disagree with a lot of those
09:05:05 rulings, and not just the cephalad migration deaths, but the buffet line e-mail, the finger picture. There's a lot of things in this case that are unfairly prejudicial and irrelevant.

Smoking is the same thing. Plaintiffs just --
09:05:19 defense just wants to get this in to say that she's a smoker and she doesn't care about her health, and that is unfairly prejudicial and irrelevant.

So you already ruled on this, Your Honor. So the question is whether the plaintiffs opened the door.

09:05:32 All we've talked about is causation relating to the filter. And that's all that Dr. Muehrcke talked about, and that is all Dr. Hurst is going to talk about as far as what could happen from her respirations could cause the filter piece to move and migrate and cause harm.

09:05:51 They don't have any experts disclosed in this case that are going to talk about causation as far as smoking shortening her life, or anemia or hypertension or any of these things. There's no medical testimony about causation in this case from them. We haven't opened the door.

09:06:08 As far as pain and suffering, that's from the

09:06:10 removal. And our experts have been clear about that and clear about that in their reports.

They've already briefed this, Your Honor. They've already argued it. I know we've got the jury waiting, so I 09:06:21 won't be further, Your Honor, but the Court's already ruled on this, and we believe the Court should reaffirm its rulings because plaintiffs have not opened the door. And will not.

THE COURT: Okay. I understand your positions. We'll look at those cases and then we can talk about it later 09:06:35 in the morning when the plaintiff testifies.

MS. HELM: Excuse me. Respectfully, Your Honor, it impacts Dr. Hurst's cross-examination, as I stated. I know we have the jury and I'm mindful of it, but it does make a difference in Dr. Hurst's cross-examination.

09:06:50 THE COURT: Well, I've got to read the cases. Right? I don't know what to do about that because I didn't learn about the cases until this morning, and we've got to look at the cases. So we'll do our best with that.

MR. ROGERS: And, Your Honor, the cross-examination 09:07:00 of Dr. Hurst can certainly begin before the morning break. And I don't know if you can look at them on the morning break. If you can't, that's fine. Then we'll figure out a way --

THE COURT: I don't know if I can either. I'll do my best.

09:07:10 MR. ROGERS: Understand, Your Honor.

09:07:10 THE COURT: There's usually several things waiting when I walk off the bench.

Okay. We'll bring the jury in.

(The jury entered the courtroom at 9:08.)

09:08:30 THE COURT: Please be seated.

Good morning, ladies and gentlemen.

THE JURORS: Morning.

THE COURT: Hope you had a nice weekend. Thank you for being here. I apologize for starting ten minutes late but

09:08:39 we had a number of issues we needed to talk through and hopefully by doing that we save time later in the trial.

We are going to continue this morning with the videotaped testimony of Ms. Hudnall.

We can proceed.

09:09:13 (Video testimony of Janet Hudnall was played.)

THE COURTROOM DEPUTY: The jury has it. I'll work on the back screen.

MR. CLARK: Your Honor, at this time the plaintiff would move the following exhibits into evidence: 4407, 4403,

09:12:40 4404, 4405, 4406, 4536, 4537, 4459, 932, 2238, 4420, subject to redaction, 79, 1006.

THE COURT: 79 meaning 79?

MR. CLARK: 79.

THE COURT: Okay. And what was the next one?

09:13:18 MR. CLARK: 1006. 1023.

09:13:24 THE COURT: I'm sorry, I couldn't hear that.

MR. CLARK: 1023, 1369, 1383, 2059, 2061, 2062, 2063, 2065, 2068, 2069, 1370, 1580, 677, 1133, 5303, 2052, 546 subject to redaction, 854 subject to redaction, 447, 1612, 09:14:19 2057 subject to redaction, 926 subject to redaction, 1295, 4412, 2052, 614, 4486, 5296, 5302, 2253.

MS. HELM: Your Honor, I tried to keep up with Mr. Clark but my list is in a different order than his, so may I have an opportunity to review his list before I state 09:15:01 whether I have any objections or not?

THE COURT: Yes.

MS. HELM: Thank you.

THE COURT: Mr. Combs, what are we doing next?

MR. COMBS: Plaintiff calls Dr. Darren Hurst.

09:15:35 THE COURT: Ms. Helm, after you've looked that over, if you could just, even in the middle of Dr. Hurst, let me know how you rule so we know if these exhibits are in for purposes of his testimony.

MS. HELM: Yes, Your Honor, I'm going to --

09:15:46 THE COURT: Whenever you can get through it.

MS. HELM: Thank you.

THE COURTROOM DEPUTY: Dr. Hurst, if you would please come forward and raise your right hand.

09:16:19

DARREN R. HURST, M.D.,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

THE COURTROOM DEPUTY: Would you please state and

09:16:19 spell your name for the record, please.

THE WITNESS: Darren Robert Hurst. D-A-R-R-E-N. R-O-B-E-R-T. H-U-R-S-T.

D I R E C T E X A M I N A T I O N

BY MR. COMBS:

09:16:40 Q Good morning, Dr. Hurst. When you get settled there, if you could please introduce yourself to the jury.

A Excellent. Yes.

Hi. My name is Darren Hurst. I'm a physician. I work in northern Kentucky in the Greater Cincinnati area. I'm

09:17:29 a vascular and interventional radiologist.

Q And, Dr. Hurst, could you briefly explain what you do as an interventional radiologist.

A Yeah. So interventional radiologists are physicians who use image-guided minimally invasive therapies to treat

09:17:45 patients, predominantly with vascular disease, but with cancer as well. We do vascular access, dialysis access, place bal- -- use balloons and stents to treat vascular disease and place IVC filters.

Q So in your practice you do use IVC filters?

09:18:04 A Yes.

09:18:04 Q Have you implanted IVC filters?
A Yes.
Q Have you removed them?
A Yes.
09:18:09 Q And does that include Bard IVC filters?
A Yes.
Q And why don't you tell the jury why you're here today and what your role is in this case.
A So my role in this case is to evaluate the performance of
09:18:24 the Bard Eclipse filter in Doris Jones and to evaluate whether the implanting physicians were adequately warned of the potential risks and complications of the device, and also to evaluate the modes of failure of the device.
Q And did you review Mrs. Jones' medical records and
09:18:49 imaging?
A Yes.
Q And are you going today to explain that imaging as it relates to Mrs. Jones and her filter?
A Yes.
09:19:00 Q And what did you find when you reviewed the imaging in regards to her filter?
A So Mrs. Jones' filter demonstrated multiple modes of failure, including tilt, migration, fracture, and embolization of one of the fragments of the filter through her heart to her
09:19:17 right pulmonary artery.

09:19:20 Q And let's talk about your education and background briefly.

You're a doctor specializing in vascular and interventional radiology; correct?

09:19:29 A Yes.

Q Where are you licensed to practice vascular and interventional radiology?

A Indiana, Ohio, and north -- I'm sorry, and Kentucky.

Q And where did you go to school to obtain your medical

09:19:40 degree?

A The University of Cincinnati.

Q If could you briefly describe your training after medical school.

A So after medical school I went to the University of

09:19:50 Michigan and did a diagnostic radiology residency for four years. And then, following that, a year of training in vascular and interventional radiology as a fellow at University of Michigan.

Q So how long have you been a doctor?

09:20:05 A 21 years.

Q And where do you work now?

A I work at St. Elizabeth Health System. It's a large medical system in northern Kentucky that covers the southern part of Greater Cincinnati. We have three hospitals with over

09:20:20 a thousand beds. We're a tertiary care medical center.

09:20:25 Q And what positions do you hold in your hospital system?
A So I've been the director of vascular interventional radiology for the system for ten years, and then I'm also the chair of the product committee, which evaluates all the
09:20:40 products that come through the cardiology cath lab and the interventional vascular labs.
Q Are you board certified?
A Yes, I'm board-certified in both vascular and interventional radiology and diagnostic radiology.
09:20:54 Q How long have you been board certified?
A Since 2001.
Q And could you briefly explain to the jury, I think we're all familiar with the radiologists if you go in for imaging, that would be what's called diagnostic radiology?
09:21:08 A Yes.
Q Can you explain the difference between a diagnostic radiologist and an interventional radiologist?
A So an interventional radiologist is basically like a vascular surgeon, except I don't do open surgery. I run my
09:21:20 own clinics, I see patients with vascular diseases like varicose veins, arterial disease like vascular disease that affects the iliac arteries or the renal arteries or the arteries of the legs. And we also see cancer patients that have issues with liver tumors that we embolize. It's a wide
09:21:42 variety of diseases that are treated with minimally invasive

09:21:46 therapies.
Q Now, you are here as an expert witness. You never treated Mrs. Jones.
A No.
09:21:54 Q And you talked about you'd spent time reviewing her records and imaging. How much time overall do you think you've spent working on this case?
A Probably about 30 hours.
Q And have you been paid for that time?
09:22:07 A Yes.
Q What percentage, if you could give it a percentage, of your professional work is doing litigation work, expert witness work like this?
A About 10 percent of my time is spent doing that.
09:22:22 Q And how much do you charge for your litigation work?
A $500 an hour.
Q And about how much do you think you've been paid total by the plaintiff for your work on this case?
A Probably about $25,000.
09:22:41 Q And what did you do to prepare to come here today through this case in preparing opinions?
A So what I did was I reviewed all of Doris Jones' medical records, all of her imaging that was pertinent to the case. I reviewed the Bard internal corporate documents that were
09:23:00 provided to me. I've reviewed the medical literature that is

09:23:06 pertinent to this case. And I've reviewed the instructions for use for various devices, including the Eclipse filter. Also reviewed the depositions and expert witness reports for both sides.

09:23:22 Q And then you prepared a report in this case, a summary of your opinions?

A Yes.

Q When you were reviewing the imaging for Mrs. Jones, what was important to you to look at in reviewing the imaging?

09:23:38 A So when we look at filters on imaging, what we're looking at is the degree of tilt present in the inferior vena cava from the filter; migration, either towards the head, which is cranially, or towards the feet, which is caudal; the presence of fracture and the presence of fracture fragments or

09:24:05 fragments that have embolized or gone through the vascular system.

Q And you talked about you have used Bard filters in the past. What Bard filters have you used?

A So we used the permanent filter, the Simon Nitinol filter.

09:24:20 Then we used the Recovery, the G2, the G2X, the Meridian, the Eclipse, and the Denali.

Q Do you still use those filters today?

A The only filter that is still available today is the Denali. The rest have been removed from the market.

09:24:41 Q And did you bring a couple filters with you here today?

09:24:44 A I did, yes.
Q And if you could -- do you have a G2 filter?
A Yes.
MR. COMBS: Your Honor, I'd like to -- I'm not sure
09:24:58 if I know how to do it, to turn on the Elmo there, if I may approach?
THE COURT: Traci can do it.
MR. COMBS: Okay.
Thank you, Traci.
09:25:13 THE WITNESS: Sorry, these filters tend to like each other very much.
There we go.
I also have this one.
BY MR. COMBS:
09:25:26 Q Let's just get the G2 out to start.
A Sure.
Q And if you could -- and I understand the filter that's at issue in this case was an Eclipse filter; correct?
A Yes.
09:25:47 Q Do you have an Eclipse filter up there with you?
A I do.
Q Oh, you do. Okay. I'm sorry, then let's get the Eclipse filter out. I'm the one confusing the jury.
A There you go.
09:25:58 Q If could you just talk briefly about the Eclipse filter.

09:26:02 A So --

MR. ROGERS: Your Honor, I'm sorry to interrupt. I don't believe this was disclosed in Dr. Hurst's report. A general description of the filter and how it works, the

09:26:10 Eclipse filter.

THE COURT: Where is it in the report?

MR. COMBS: The top of page 10, Your Honor. I understand the question was a little open-ended. I can rephrase it, but --

09:26:41 And if we're going to deal with objections, I can be more specific in my questions, Your Honor.

THE COURT: Yeah, let's do that, please.

MR. COMBS: Understood. I'll withdraw that.

THE COURT: Do you want this displayed to the jury?

09:26:53 MR. COMBS: Oh, I'm sorry. Please. If I could publish to the jury, Your Honor.

THE COURT: All right. You may.

MS. HELM: I'm ready when you are, Your Honor, on the exhibits.

09:27:03 THE COURT: On the exhibits?

MS. HELM: Yes.

THE COURT: Are you going to be using any of the exhibits that were listed, Mr. Combs?

MR. COMBS: I'm not 100 percent sure. I don't think

09:27:12 so.

09:27:13 THE COURT: Then why don't we -- let's wait and do those after the direct, if that's all right.

MR. COMBS: If one comes up, I'd be free to --

THE COURT: Yeah. Okay.

09:27:22 MR. COMBS: Okay.

BY MR. COMBS:

Q Dr. Hurst, I believe you've testified before that the Eclipse filter has a conical design. Could you talk about what that means, explain that to the jury.

09:27:38 A Sure. So the conical design means that the filter is shaped like a cone. Like a teepee, basically, without the fabric on it. Some filters are shaped like that. Other filters have a less conical design. But the whole family of Bard filters all had a -- were based off a conical design or a

09:28:04 tent-like design where the arms and legs meet at the top of the cone.

Q And what's the difference -- what was the predecessor device of the Eclipse filter?

A The G2X.

09:28:23 Q And what was the predecessor device of the G2X?

A The G2.

Q And, first, what was the difference between the G2 and G2X?

A The G2, which is this device right here, did not have a

09:28:37 hook on the top.

09:28:39 I'm going to rotate this one so that you can see the retrieval hook. You can barely see it.

At the top of the -- this device there is a tiny little hook, and that's to facilitate retrieval of the device 09:28:58 from the inferior vena cava. The original device, the original G2 did not have a hook.

Q And then the G2X was the predicate device for the Eclipse filter; right?

A Correct.

09:29:17 Q And what was the difference between the G2X and the Eclipse?

A So the G2X and the Eclipse are different in that the Eclipse filter is actually what we call electropolished. And you can see that this filter is shinier. It reflects the 09:29:38 light much better than the predecessor. The electropolishing was the main difference between the two filters. That, and the color is different. It's blue.

Q And you've talked about in your report and testified about the Simon Nitinol filter; correct?

09:30:03 A Yes.

Q And what was the Simon Nitinol filter?

A So the Simon Nitinol filter is this device right here. It is a permanent filter that has a slightly larger diameter wire than the two retrievable filters. It does not have a hook. 09:30:26 It has a large continuous cone, or they look like petals on a

09:30:33 flower. That is one continuous wire that is woven around to also -- to -- the idea was to additionally trap a clot. It also has larger hooks on its feet. And it has a wider spread of its legs than the G2.

09:30:56 MR. COMBS: Your Honor, at this time we would ask if we could publish those to the jury for them to hold, like we did with Dr. McMeeking.

THE COURT: Any objection?

MR. ROGERS: No, Your Honor.

09:31:05 THE COURT: Yes, that's fine.

Why don't we have Traci do that.

MR. COMBS: And, Your Honor, if I could continue with my examination of Dr. Hurst while the jury's examining it? It's up to you.

09:31:18 THE COURT: Well, then they're going to be having to split their attention. If you want them to look at the filters, I'd rather not have them having to listen to the witness at the same time.

MR. COMBS: Understood, Your Honor.

09:35:35 BY MR. COMBS:

Q Dr. Hurst -- oh, I'm sorry, not quite done.

Now we have them all.

Dr. Hurst, could you explain to the jury about the differences between permanent and retrievable filters.

09:35:57 A So permanent filters were the original devices to be used

09:36:04 for what we call caval interruption. So an inferior vena cava filter is placed when a patient has a contraindication to the primary way of treating DVT and PE, which is anticoagulation. So if you can't give a patient blood thinner to treat their
09:36:27 DVT or PE, then the next option is to place a filter. The initial devices were permanent devices, and they were placed in the inferior vena cava.

Q And, Doctor, make sure they can see it --

A Yeah, I've got to get it in there.

09:36:51 They're placed in the inferior vena cava through a catheter. The device is folded up inside a catheter and then delivered into the inferior vena cava. Folding them up again usually is a lot more difficult than it was to initially deploy them.

09:37:10 There we go.

So if you can imagine this as the -- this tube as the inferior vena cava and the patient's legs are down here, what the device does is it blocks clot from traveling from the legs through the inferior vena cava to the lungs up here, where it
09:37:29 can have deadly consequences.

What happens is the clot travels through the inferior vena cava, hits the filter, either breaks up in the filter to smaller clots which don't affect the lungs and heart as much, or it's trapped in the filter for a long enough period of time
09:37:49 that the body can break down that clot naturally.

09:37:55 So these devices were made to stay in the patient permanently. They can be retrieved but it's an extremely difficult procedure and rarely -- it's rarely done.

The retrievable filters were a new class of device 09:38:14 that could be placed in the inferior vena cava and because of their design, with legs that had hooks that were smaller and were designed to release from the inferior vena cava wall and also the device itself had less radial force or outward force on the inferior vena cava, the device could be retrieved by 09:38:41 placing a -- by hooking the device with a snare from above and then running a catheter over the top and collapsing the device into a catheter, and then removing it.

Q And, Dr. Hurst, what are the circumstances when a patient requires an IVC filter?

09:39:01 A So the main circumstance is a contraindication to anticoagulation and a history of DVT and PE. And contraindications to anticoagulation can include patients with, like, a brain tumor. You can't put those patients on a blood thinner because they might bleed into their head. Or 09:39:22 maybe a history of recent falls. You don't want those patients on a blood thinner because they could fall and hurt themselves and bleed out.

The other indication is a patient who is at high risk for DVT and PE and who has had a PE or a DVT while on 09:39:37 anticoagulation. And those patients sometimes have issues

09:39:41 with diseases involving the blood that cause them to clot more commonly than other patients.

Q And I think we can put those away and turn that off.

MR. COMBS: And then, Gay, if you could please pull

09:39:56 up Exhibit 4428.

Which I believe is in evidence, Your Honor.

THE COURTROOM DEPUTY: What was the number?

MR. COMBS: 4428.

THE COURTROOM DEPUTY: Yes, sir.

09:40:17 MR. COMBS: May I publish it to the jury?

THE COURT: You may.

BY MR. COMBS:

Q And, Dr. Hurst, in your practice you receive marketing brochures like this for various products?

09:40:25 A Yes.

Q Including Bard products?

A Yes.

Q Are you familiar with this brochure?

A Yes. As part of the product committee, we review the

09:40:34 marketing materials and the instructions for use for the devices that are being submitted to the committee for purchase by the hospital.

MR. COMBS: And if you could go to the next page, Gay.

09:40:51 And --

09:40:55 MR. ROGERS: Your Honor, I'm sorry to interrupt, but I don't believe that the doctor has disclosed any information about this particular brochure in his report.

THE COURT: Mr. Combs?

09:41:20 MR. COMBS: I would direct Your Honor to page 9 of his report, Roman numeral IV.

THE COURT: Are you going to ask specifically about that opinion?

MR. COMBS: Yes.

09:41:46 THE COURT: Mr. Rogers?

MR. ROGERS: Your Honor, in that portion of the report it does not mention this particular document. So -- I mean, it's a relatively broad statement.

THE COURT: I agree, but I'm going to overrule the

09:42:01 objection.

But you ought to focus on that opinion in your questioning.

MR. COMBS: Understood, Your Honor.

BY MR. COMBS:

09:42:15 Q This brochure here talks about electropolishing, Dr. Hurst?

A Yes.

Q Did the -- could you point to where on this it talks about electropolishing?

09:42:38 MR. ROGERS: Your Honor, I'm sorry to interject

09:42:40 myself again, but the statement that Mr. Combs directed us to does not mention electropolishing. It doesn't talk about that. So I think it's beyond his report.

THE COURT: Your response, Mr. Combs?

09:42:54 MR. COMBS: Your Honor, his report discloses -- I need to lay a -- tell him what I can ask him about. I don't think it needs to describe exactly every marketing material, the problems with it.

THE COURT: Well, this is the difficulty in line 09:43:07 drawing that we referred to this morning. I think you need to stick to the opinions and not go beyond it. I'll allow you to lay the foundation briefly for his opinion on this brochure that he stated in his report, but you shouldn't be going beyond that opinion.

09:43:23 MR. COMBS: Understood, Your Honor. That's all I'm trying to do.

BY MR. COMBS:

Q Dr. Hurst, can you describe on there where it talks about electropolishing?

09:43:32 A Yes. The electropolished Eclipse vena cava filter combines proven performance with long-term retrievability and improved surface.

Q And what is your opinion on the Bard marketing materials that you reviewed for this case and the claims they make in 09:43:49 their marketing materials?

09:43:51 A So the claims in the marketing materials don't seem to jibe or correlate with the claims in the instructions for use. The marketing materials often talk about increased stability, increased centering capability, migration resistance, when we 09:44:10 know that these devices have issues with all of those particular problems.

Q Let's turn to Mrs. Jones' medical course.

And can you just briefly describe her medical course as you -- regards to her filter based on your review of the 09:44:37 records and imaging?

A Sure. Hold on, let me pull up my report here.

So Mrs. Jones had gastrointestinal issues related to ulcers and bleeding, and she required surgery for those ulcers. It's a pretty significant issue. And because she was 09:44:58 having -- I'm sorry -- and during this time where she was having all these issues, she also developed a DVT. So she needed protection from pulmonary embolism, but at that time, because she was having issues with bleeding, her anticoagulation was contraindicated, so they chose to place an 09:45:22 IVC filter.

And following that, she developed issues with her IVC filter and developed chest pain and presented to the emergency department with chest and arm pain, and was found to have a fragment of the filter in her right pulmonary artery.

09:45:46 Q And what happened with her filter after that?

09:45:52 A So because of the -- well, her physicians decided that they felt that the filter was unstable and that she didn't need it anymore, so there was very little benefit that she would gain from having the device that had some instability 09:46:09 and had already fractured. So they removed her Eclipse filter from her inferior vena cava.

Q And you reviewed -- how much imaging for Mrs. Jones did you review in this case?

A There's about 20 or 30 studies and 800 or so images.

09:46:29 Q Were those images useful to you in formulating your opinions in this case?

A Yes.

Q And what I'd like to do is have you walk us through some of those images.

09:46:44 MR. COMBS: Gay, if you could pull up 4574.

MR. ROGERS: Your Honor, I apologize. I object. There is nothing about this particular image in Dr. Hurst's report.

THE COURT: Why don't we talk for a minute at 09:46:58 sidebar, Counsel.

Ladies and gentlemen, if you want to stand up, feel free to do that.

(Bench conference as follows:)

THE COURT: Is this image discussed?

09:47:26 MR. COMBS: It's in his review list. It's not

09:47:29 discussed specifically. As you know, Your Honor, our position is that requiring a script of trial testimony for an expert is not the proper interpretation of the disclosure requirements. There's case law to the effect that a physician has -- or any 09:47:48 expert can talk about things that are reasonably within their expertise and that you don't need a script of testimony.

I understand Your Honor takes a different position, so I'm just making that record here.

But his report does talk about specific imaging and 09:48:02 he talked about specific events in Mrs. Jones' medical history.

THE COURT: Tell me where that is, please.

MR. COMBS: Page 5.

And there are other opinions about tilt of the filter 09:48:32 or things that are -- obviously elsewhere in his opinion.

THE COURT: Where on page 5?

MR. COMBS: B.

THE COURT: B?

MR. COMBS: Yes.

09:48:53 THE COURT: So Dr. Avino's placement of the filter?

MR. COMBS: Yeah. These are all --

THE COURT: Is that what you are going to have him describe now from this exhibit?

MR. COMBS: Correct.

09:49:03 THE COURT: And the exhibit that you're presenting to

09:49:08 him, is it one of the images reviewed? And if so, which one?

MR. COMBS: This one wasn't actually on his imaging list because we didn't get it to him at the time of his report, but we did supplement it later and get it to him.

09:49:22 THE COURT: Did you supplement the report later?

MR. COMBS: I don't believe we did, Your Honor.

THE COURT: Well, here's -- hold on, please.

Here's the problem that I have. It seems to me we're either going to adhere to Rule 26 or we're not. Rule 26 says

09:49:35 that any exhibit the expert is going to use in trial has to be included with the expert report. That's right in the text of Rule 26(a)(2)(B).

I don't believe that the requirement is that an expert only speak a word or a sentence that's in the report.

09:49:54 But I believe the report has to describe the testimony. In fact, that's what the committee note to Rule 26(a)(2)(B) says, it's intended to disclose what the expert will say on direct testimony.

And it seems to me we either hold all experts to that

09:50:14 standard or we hold none. I will tell you I've never had a case of trial in 15 years where I have relaxed that standard, because I think it's the only way fair way to proceed.

So if you're going to put in front of this expert an exhibit for purposes of trial that was not in the report,

09:50:30 that's clearly not allowed by Rule 26(a)(2)(B).

But I'm going to hold all experts to the same standard, including the defense experts, as I think I did in the Booker trial.

Now, I say that so I can hear your response.

MR. COMBS: No, I understand that, Your Honor. And I think there's, I think, five images we wanted him to show. I think that is the only one that's not in this reference list. But I think -- that's my position on that.

THE COURT: Nancy, did you find that yet?

So I just want to be real clear since this is going to be on the record. What I am referring to is the requirement in Rule 26(a)(2)(B)(iii) that the report must contain, quote, any exhibits that will be used to summarize or support them, meaning the opinions that the expert is giving, it has to be in the report.

So just so we're complete on the record, Docket 519, which is Case Management Order Number 8 in this case, says that the parties were required to provide, quote, full and complete expert disclosures as required by Rule 26(a)(2)(A) through (C).

And then, on page 3 of the report, I said -- this is paragraph 6 on page 3: As stated in the advisory committee notes to Rule 26, expert reports under Rule 26(a)(2)(B) must set forth, quote, the testimony the expert is expected to present during direct examination together with the reasons

09:52:37 therefor, close quote.

I went on to say full and complete disclosures of such testimony are required on the dates set forth above.

I did that to try to be as clear as I could that I 09:52:49 was going to apply Rule 26 literally. So my conclusion is that an expert cannot use an exhibit that was not disclosed in the report.

But I'm not going to say you can only speak a sentence if it appears in the report. You can give that 09:53:05 testimony, but the testimony has to be disclosed in the report, and the exhibits do too.

MR. COMBS: And our argument wasn't that you were saying that, Your Honor. The argument is that if opinion is disclosed in a report on a topic where he says he reviewed 09:53:21 imaging, an expert within his expertise should be allowed to talk about that, especially given factual testimony and like -- like where the filter went -- fragment went afterwards. That's not even opinion or disputed. There's certainly no issue with nondisclosure, any surprise to Bard 09:53:38 whatever, and our position, these are technical objections that Bard is making, and so experts should be allowed to talk about things within their expertise, especially if they're factual matters and not even opinion. Like reviewing records and imaging.

09:53:56 MR. ROGERS: Your Honor, regarding this particular

09:53:58 exhibit that plaintiff wants to use, Mr. Combs already said this was not in his report. He had not looked at this film at the time of his report. It was not mentioned in his report. He does say that Dr. Avino implanted the filter and lists a
09:54:14 position. But, you know, Your Honor, I assume that that was just lifted from the medical record because that is exactly what Dr. Avino says in his document, his implantation record.

And so it's clear that this witness had not seen this image at the time of the report. So I don't think,
09:54:32 Your Honor, it is fair for him to be able to talk about it now at trial.

THE COURT: All right. I understand both parties' positions. I'm going to sustain the objection and stick with what I tried to clearly state in Case Management Order
09:54:44 Number 8 on all experts, including defense experts --

MR. ROGERS: Understand.

THE COURT: -- that are going to be held to the same standard. So I'm going to sustain the objection to the use of this exhibit.

09:54:52 MR. COMBS: Your Honor, can we go ahead, we're here, and talk about the next image I'm going to show, which is something that's in his reliance list. Can I ask him opinions about that, or is that going to get another Bard objection?

THE COURT: Well, tell me what it is and where it is.
09:55:05 And I don't want to keep the jury waiting too much longer.

09:55:09 MR. COMBS: His reliance list. It's going to be the 8/14/13 chest and rib X-ray on page 4.

THE COURT: Okay. What do you intend to do? Where's the testimony or opinion regarding that disclosed in his

09:55:32 report?

MR. COMBS: I don't know if that is specifically described in his report either, but it is on part of his reliance list and, like I said, Your Honor, I think someone within their expertise can talk about what that image shows,

09:56:05 opinion.

THE COURT: I disagree with that. I think it needs to be in the report if the expert is going to give it. So if it's not described then -- in the report or the deposition. I think I also said in my case management order that if the

09:56:14 other side pulls stuff out of the expert at deposition, that becomes fair game. If it's not discussed in those, then I'm going to sustain the objection.

MR. ROGERS: And, Your Honor, in an effort to move this along I would go ahead and say that it's my position that

09:56:31 the doctor does address the CT scan in his report. So I would have no disclosure objection to the CT scan.

As far as any other imaging, he has no specific comment except for just listing out images that he's reviewed. So that's what I'm planning on sticking to. I'm just trying

09:56:47 to let Mr. Combs know.

09:56:49 THE COURT: What I'm going to look for is, is the exhibit mentioned in the report and testimony that will be given about it.

MR. COMBS: Thank you, Your Honor.

09:56:57 MR. ROGERS: Thank you, Your Honor.

(Bench conference concludes.)

THE COURT: Thanks, ladies and gentlemen.

MR. COMBS: Gay, you can take that one down for now.

BY MR. COMBS:

09:57:16 Q Dr. Hurst, we talked about the filter was implanted in 2015 -- I mean, I'm sorry, 2010 --

A Yes.

Q -- correct?

By Dr. Avino?

09:57:26 A Yes.

Q Was it appropriate to implant a filter in Mrs. Jones at the time?

A Yes.

Q And in your review of this case, did you find anything

09:57:38 that Dr. Avino did wrong as far as implanting the filter?

A No. When he implanted the filter it was appropriately positioned with the superior tip at the L2-L3 intervertebral body level, or disk level. The filter was centered in the inferior vena cava and --

09:57:56 MR. ROGERS: I apologize, again, Your Honor. I don't

09:57:58 want to continue to interrupt, but the witness has continued to talk about the image and we just discussed this issue.

THE COURT: Let's ask the next question, please, Mr. Combs.

09:58:08 MR. COMBS: Thank you, Your Honor.

BY MR. COMBS:

Q And then you talked about in 2015 the filter was discovered to be fractured; correct?

A Correct.

09:58:26 Q Let's -- what happened to the filter fragment after it broke off from the Eclipse filter?

A So when a fragment embolizes or migrates away from the filter, it -- when it fractures and becomes a free fragment, it travels through the inferior vena cava with the flow of

09:58:51 blood back towards the heart, through the right atrium, through the valve, through the right ventricle and into the pulmonary artery, and then out to where it ended up, the right pulmonary artery.

MR. COMBS: And, Gay, if you could pull up 4570.

09:59:09 BY MR. COMBS:

Q And, Doctor, what is 4570 on your screen there?

A This is a coronal, so a front view, multiplanar reconstruction of a CT examination, a CAT scan study.

Q And what is the date on that, do you know?

09:59:35 A 4/22/15.

09:59:39 MR. COMBS: Your Honor, I ask to move 4570 into evidence.

MR. ROGERS: No objection, Your Honor.

THE COURT: Admitted.

09:59:46 (Exhibit 4570 admitted.)

MR. COMBS: And publish to the jury, Your Honor?

THE COURT: You may.

MR. COMBS: Thank you, Your Honor.

BY MR. COMBS:

09:59:54 Q So, Dr. Hurst, if you could describe what the jury is seeing on their screens here --

A Sure.

Q -- for us.

A So this structure right here is the right atrium. 10:00:10 Normally that connects up to the right ventricle. You don't see it very well here, but this is the right ventricle. There will be a valve right here, and then because of the way this image is done it's like a slice through the chest at a certain level. What you're act- -- you're actually missing the part 10:00:34 of the pulmonary artery which comes off this way and goes up like that to the main pulmonary artery up here.

And then this is the right pulmonary artery, and that goes to the right middle of the pulmonary artery where the fragment is situated.

10:01:00 Q And from the imaging you reviewed, specifically this CT

10:01:03 scan, and I understand there's different slices you can view?
A Yes.
Q How many slices or images from this CT have you reviewed approximately?
10:01:12 A Oh, there's 3- or 400, at least.
Q From your review of this exhibit, 4570, what can you tell the jury about the current -- or I guess current as of the time of this CT scan, location and status of the fragment in the pulmonary artery?
10:01:32 A So the fragment is located in the right middle lobe pulmonary artery. It extends down into the peripheral portion of the artery of the segmental branch. The fragment itself, a portion of it is along the wall of the artery, and then a portion of it is free within the pulmonary artery.
10:01:59 Q And what risk does that create for Mrs. Jones, that fragment in her pulmonary artery?
A There are a few risks. The first risk is that this pulmonary artery -- or that this fragment could migrate more distal into a smaller pulmonary artery and cause occlusion of
10:02:20 the pulmonary artery segment.
Another risk would be that this fragment, which has basically two sharp ends, could penetrate through the pulmonary artery and cause hemorrhage into either the lung or into the mediastinum or its structure surrounding the heart
10:02:42 into the chest, which could be catastrophic or

10:02:45 life-threatening.

The final complication that could occur would be that this fragment could migrate distally and puncture the lung itself, the airways of the lung, and result in what is called
10:03:03 a pneumothorax, which is when the lung actually collapses. That also can be a catastrophic or very serious event.

The final, but most least likely, would be that the fragment itself could serve as a nidus for infection. So if she was getting her teeth cleaned or having an IV placed or
10:03:26 anything that could introduce a small amount of bacteria into her blood, this could serve as a sort of stopping ground for that bacteria and result in an infection.

Q And can you quantify with some kind of number on what kind of risk Mrs. Jones faces from those conditions you just
10:03:44 described?

A I don't think we really actually know what the risk is. Because we really don't have a lot of experience with fragments traveling to the pulmonary arteries, there are not a whole lot of studies. We don't really know exactly what is
10:04:03 going to happen with this fragment in her pulmonary artery.

Q What do you think happened to Mrs. Doris Jones' Eclipse filter?

A What do I think happened to Doris Jones' Eclipse filter. Well, in this family of devices we saw a cascade of failures
10:04:34 that begins with the caudal migration. When the filter

10:04:37 migrates or settles in the inferior vena cava, the legs start to splay out and become more horizontal.

So if we're looking at the device, the device would tilt sideways in the inferior vena cava, and as it tilts 10:05:04 sideways these legs start to catch the other, the opposite wall of the inferior vena cava, and there's new horizontal pressure put on that leg, kind of like this. Those legs aren't used to having that kind of sideways or horizontal pressure. They're really only supposed to have pressure that 10:05:23 goes up and down like this. But when it turns sideways or even a little sideways, that pressure in the cava or that movement in the cava starts to wrench at it, kind of like this.

This particular device, the G2, Recovery -- this 10:05:40 family of devices, I'm sorry, is different than the permanent filters in that it has the cone of arms that you guys saw, where there's only one attachment point for this arm. It's at the top or the tip of the device. Whereas the Simon Nitinol, that is one continuous wire, so if it breaks it has two 10:06:03 attachment points. Because it has only one attachment point, if this breaks free, there is a higher risk that it can go anywhere.

So I think in her particular case, one of these arms got caught up on the sidewall of the inferior vena cava when 10:06:25 this tilted a small amount, and then fractured and traveled

10:06:28 through her inferior vena cava, through her right atrium, through her right ventricle, and into her pulmonary artery.

Q Change topics a little bit here.

Dr. Hurst, what is informed consent? And

10:06:42 specifically when you're talking about implanting a permanent medical device in a patient like an IVC filter?

A So when we plant -- implant permanent devices in patients, we're kind of serving as the informant for the patient. We're making a decision together based on the -- my knowledge of the

10:07:08 device and its behavior and its potential benefits and the patient's disease process and the risks of that ongoing disease process.

So we do a risk/benefit analysis, and it really depends on the inherent or potential risks of that device.

10:07:29 You really need to know what's going to happen with that device before you place it.

Q So when you're assessing the risk/benefit analysis, so you can provide informed consent to a patient, do you have expectations of a medical device company like Bard?

10:07:48 A Yes.

Q What are those expectations?

A We expect the device companies to provide us with information that will instruct us on how to use the device properly, instruct us on or warn us of potential complications

10:08:03 that occur both during the placement of the device and in the

10:08:07 follow-up of the device. We expect to be instructed on how to follow up the device, especially if it's a permanent device. And we expect to kind of have an idea of what the incidence of and seriousness of these potential complications of any device 10:08:27 would be.

Q And you just talked about the expectations of a company as far as of information it would provide to you.

What were your expectations yourself and similar interventional radiologies as far as the performance of the 10:08:44 Bard IVC filters, including the Eclipse?

A So we expect the device company up front to have done their due diligence, to have done the research on the device, to understand how the device will work in a patient. And then, once the device is released, we expect communication 10:09:02 back and forth on any adverse events that they might be seeing or any risks that are unexpected that occur with the device. We expect them to have some sort of surveillance program such that they'll be able to alert us to issues that are happening with the device.

10:09:25 Q And as far as the performance of the device, did Mrs. Jones' Eclipse filter meet those expectations?

A Mrs. Jones' filter did not. Unfortunately, it failed. It developed a fracture which embolized or migrated to her heart and then to her right pulmonary artery.

10:09:46 Q Now, the Eclipse was -- could be a permanent device?

10:09:51 A The Eclipse was marketed as both a retrievable and permanent device, yes.
Q Was there a specific expectation of interventional radiologists at the time when Doris Jones' Eclipse filter was
10:10:06 implanted in August of 2010 as to how it would performance as a permanent device?
A Well, when we placed permanent filters in the past, like the Simon Nitinol filter and the Greenfield filter, the expectation is that those filters would remain stable in the
10:10:19 patient, not move, and provide protection for the patient's lifetime.
Q And if a new version of an IVC filter was put on the market, what would physicians like yourself have reasonably expected the manufacturer to have done before putting a new
10:10:44 device out on the market?
A The same things that we would expect with the permanent devices. I mean, we would expect they would have done the research to evaluate the behavior of the device. And for a device that was going to be permanent, you want them to
10:10:58 evaluate the stability of the device.
Q You talked a little bit about risk/benefit analysis in the context of informed consent.
What is your risk/benefit analysis of the Eclipse filter that Mrs. Jones received?
10:11:18 A Well, I think that the filter did not perform like it was

10:11:22 supposed to and provided very little benefit to her beyond the initial time of the placement.

So as a permanent device, it did not function very well.

10:11:38 Q Did it pass or fail risk/benefit analysis?

A As a permanent device, it failed.

Q Was there another option for -- in 2010 that would have performed better on a risk/benefit analysis?

A The Simon Nitinol filter would have, yeah.

10:11:55 Q Now, there would be an additional benefit from an Eclipse filter in that it could be retrieved, whereas the Simon Nitinol filter, I think you testified, would be difficult to receive -- to retrieve, excuse me.

How does that additional benefit affect the

10:12:12 risk/benefit analysis you just talked about?

A Well, I think it depends on how long you leave the filter in. Certainly, if you were going to leave this in a short period time, which is now the current FDA recommendation, the risk/benefit analysis changes. But over time, as you leave

10:12:29 this device in, the incidence or the risk of a complication such as a fracture, migration, penetration and such increases. So that modest benefit of retrievability is outweighed by the long-term risks of the device.

Q You talked about some of the problems that this line of

10:12:56 filters has, in your opinion. But don't all IVC filters have

10:13:04 complications?
A So all IVC filters -- actually, any device has risks when it's placed in a patient. And all IVC filters have demonstrated some complications. The difference between the
10:13:20 permanent filters, which we had a 20-or-so-year history with, and this family of devices is that each one of these devices, and I have a Greenfield filter here and a Simon Nitinol filter, but I have other filters, each one of these devices had maybe one or two issues with it that we knew about that
10:13:42 could cause a complication.

For example, the Greenfield filter, which is a conical filter, had issues with tilt. The Simon Nitinol filter had issues with penetration of the inferior vena cava.

This family of filters, though, had almost every
10:14:02 issue. It wasn't that they had just one issue, you know, tilt, one issue with penetration. It had issues with penetration, tilt, migration, and then it had a new issue of these embolized fragments, which was extremely rare but for -- before this device.
10:14:25 Q And what level of harm do these new more severe complications create?
A Well, so when we talk about complications and the severity of complications and risks, if a device like the Greenfield filter fractures, it may have very little effect on the
10:14:46 patient because that fracture fragment's not going to embolize

10:14:50 because it has two attachment points, it has very robust hooks that hook into the inferior vena cava and rarely release, and then it has a second attachment point at the cone of the filter.

10:15:02 So when a device like this fractures, the severity of the complication or the adverse event is very little or has very little effect on the patient.

When we talk about a fracture and migration of an arm of a filter such as in the Eclipse, the severity of that 10:15:26 complication could be catastrophic. You can have a puncturing of the right ventricle, you can have issues with the valves where the filter fragment gets caught in the valve and then requires open heart surgery.

So the degree of seriousness of the risk is much 10:15:45 higher in this device than the complications that we saw with the other devices.

Q And for catastrophic risk like that, what would be an acceptable rate of risk generally, across all medical devices you work with?

10:16:04 A Right. So when you look at devices in the risk/benefit analysis, like I said, you can have a complication such as a fracture or tilt of the -- that's inconsequential. You're willing to accept a higher rate of occurrence, maybe one out of 1,000 patients or one out of 10,000 patients. But when you 10:16:26 get to a catastrophic or potentially catastrophic event, your

10:16:31 tolerance for risk goes way down to one out of a million.

Take, for example, a heart valve. So if a heart valve fails, the patient will likely die. Or there'll be extremely serious consequences -- extremely serious 10:16:49 consequences. So, you know, your tolerance for that heart valve failing is one out of a million; right?

For a device like a stent that we put in the arteries, sometimes those stents will develop a small fracture, but it is inconsequential. It doesn't cause any 10:17:15 problem to the patient. So we're willing to put up with a stent fracture in, like, one out of a thousand patients because it really has no clinical significance.

MR. COMBS: Your Honor, may I use the Elmo here briefly?

10:17:27 THE COURT: Yes.

BY MR. COMBS:

Q You talked about one in a million, Dr. Hurst. Would that be a rate of --

MR. ROGERS: Your Honor, again, I apologize for 10:17:48 interrupting, but this information has never been disclosed in any report or --

MR. COMBS: Transcript 3, page 847, Your Honor.

THE COURT: I don't see this on that page, Mr. Combs. What you're putting on the Elmo.

10:18:45 MR. COMBS: All I did was convert it to a percentage,

10:18:47 Your Honor.

THE COURT: So you're referring to lines 14 through 16?

MR. COMBS: Yes, Your Honor.

10:19:02 MR. ROGERS: Your Honor, I apologize if I misheard. I thought he said page 837. Is that --

MR. COMBS: 847.

THE COURT: 847, lines 14 through 16.

MR. ROGERS: 847, and it's lines 14 through what?

10:19:25 MR. COMBS: 16.

THE COURT: 16.

MR. ROGERS: I concede the testimony, Your Honor.

THE COURT: Objection is overruled.

MR. COMBS: May I publish this, Your Honor?

10:19:43 THE COURT: Yeah.

BY MR. COMBS:

Q So, Dr. Hurst, just so we're clear, one in a million would be .001 percent; correct?

A Yes, that is correct.

10:19:50 Q That would be an acceptable risk for a catastrophic event for any medical device?

A Correct.

MR. COMBS: I'm done with that.

If you could pull up, Gay, please, 4459.

10:20:11 I'm not sure if this is in evidence or not,

10:20:24 Your Honor. I know there were a bunch moved in. Or if we need to --

THE COURT: I don't believe it is in evidence.

MR. ROGERS: It is not, Your Honor, but we have no
10:20:33 objection to admissibility.

MR. COMBS: If I could, Your Honor, move 4459 into evidence.

THE COURT: Admitted.

(Exhibit 4459 admitted.)

10:20:42 MR. COMBS: May I publish to the jury?

THE COURT: Yes.

BY MR. COMBS:

Q Dr. Hurst --

MR. COMBS: Gay, if you could go to page 4 first.

10:20:51 BY MR. COMBS:

Q And describe what Exhibit 4459 is for the jury, Dr. Hurst.

A This is called the instructions for use document for the Eclipse vena cava filter. The instructions for use is a document that goes into every package for every medical
10:21:18 device, and it provides, number one, general information on how to use the device, the indications, diagrams on how to place the device, and then it also provides precautions and warnings and lists of potential complications that you should look for.

10:21:39 And finally, it -- well, it can provide sometimes

some clinical information or research information and also provide instructions for follow-up of a permanent device.

MR. COMBS: Gay, if you could please go to, I think it's the next page.

And -- I'm sorry, next page, please.

Yeah. And the potential complications there. I believe it's subsection G, all the way down, Gay.

THE WITNESS: G? I have a much better copy here. It's a little easier to see.

MR. COMBS: Apologize to everybody.

THE WITNESS: That's okay. I can read mine.

MR. COMBS: That's the best we have.

BY MR. COMBS:

Q Dr. Hurst --

MR. ROGERS: Your Honor, I'm interrupting to be helpful.

THE COURT: I'm sorry?

MR. ROGERS: I'm interrupting to be helpful. I apologize. But if you wanted to use the exhibit from our exhibit list, I think it's much clearer.

THE COURT: What is that exhibit?

MR. COMBS: Certainly happy to. I didn't think you had a clearer one or I would have.

MR. ROGERS: Your Honor, that would be Defense Exhibit 8325.

10:23:05 THE COURT: Can you call that up, Mr. Combs?
MR. COMBS: I'm sorry, Your Honor?
THE COURT: Can you call that one up?
MR. COMBS: Yeah.
10:23:11 Can you get that? Thank you.
THE COURTROOM DEPUTY: I have it over here. Scott pulled it up.
MR. COMBS: Can we move into evidence?
THE COURT: It's up with the defense computer.
10:23:24 MR. COMBS: Oh. You've got it. Okay. Thank you.
If we can go to the page we were just looking at with potential complications. I'm not sure what page it will be on this exhibit.
THE COURT: And this is 8325?
10:23:36 MR. COMBS: Correct, Your Honor.
THE COURT: And that's not in yet, is it, Traci?
THE COURTROOM DEPUTY: No.
THE COURT: So no objection to it being admitted?
MR. ROGERS: No, Your Honor.
10:23:44 THE COURT: Okay. So we will admit 8325.
(Exhibit 8325 admitted.)
MR. COMBS: May I publish, please, Your Honor?
THE COURT: Yes.
MR. COMBS: And if you could get the whole section, please, in one.
10:23:53

10:23:55 All right.

BY MR. COMBS:

Q And, Dr. Hurst, explain to the jury what this section is briefly.

10:24:04 A So this is a list of potential complications for the Eclipse filter.

Q And you've talked a lot about the problems the Eclipse filter has caused Mrs. Jones and the risk of harm it's caused.

Are those consequences in that risk of harm, is that

10:24:22 adequately warned of in this IFU and specifically this section?

A So with this particular IFU, it presents a -- literally a laundry list of complications. This is basically a list of every single complication that could possibly occur with an

10:24:42 inferior vena cava filter. It sort of dilutes out any potential usable warning.

This particular IFU does comment on filter fractures. But the way it describes filter fractures I think grossly understates the severity or potential severity of a

10:25:05 catastrophic event. Basically what it says is filter fractures are a known complication of vena cava filters.

Without giving a number, the physician is left to assume the incidence of this particular complication is similar to the prior known devices. And that simply wasn't

10:25:27 true with this device.

10:25:34 Q And what would a interventional radiologist like yourself have reasonably expected Bard to put in its IFU for the Eclipse?

A Well, if there was a complication that they were seeing more often than others that had potentially catastrophic consequences, most device manufacturers would highlight that and possibly give an incidence of that type of complication or perhaps have some research in there that demonstrates what the occurrence is of that particular complication, instead of putting it in a long list of complications.

MR. COMBS: If you could now just zoom in on the first two bullet points.

Thank you.

BY MR. COMBS:

Q Do you see the first bullet point does have a warning about migration; right?

A Yes, sir.

Q Is there anything in this warning about migrations causing fractures?

A No.

Q Does it say anything about rates of migrations or other complications?

A No.

And, in fact, just to clarify. So when we discussed migrations in the past with inferior vena cava filters,

predominantly the permanent devices, because that's what our experience was, migrations were actually described predominantly when the device was deployed. So oftentimes when these devices were deployed they, because they have radial strength and they're loaded, compacted into a tiny catheter, like a straw, sometimes when they would come out they would almost like fire out, and that was called migration.

The other migrations that we would see were late migrations, and they were very, very rare because -- usually because the inferior vena cava was larger than the diameter of the filter, or at least at a borderline size, and then the filter legs could not engage the inferior vena cava. And that oftentimes happened right during deployment as well.

The migration that we see with this device is a delayed migration. It doesn't happen when you deliver the device. The device can look perfect on delivery. And then years, months, whenever, later, the device has changed position. And in this particular device, it was caudal migration that was the issue.

Q And you see the second bullet point there discusses filter fractures.

Do you see that?

A Yes.

Q And I expect that Mr. Rogers, in a minute when I sit down,

10:28:36 is going to talk about this, but it says, "Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complication with vena cava filters requiring their retrieval 10:28:48 of the fragment utilizing endovascular and/or surgical techniques."

And my question, Dr. Hurst, is: Well, why doesn't that adequately warn people like Doris Jones and her physicians of what happened to her and the risk she faced with 10:29:03 the Eclipse filter?

A Because filter fractures were known complication of vena cava filters. In the permanent filters, like I said, when they fractured, though, there was -- it is extremely rare to have any clinical consequence.

10:29:18 So to say that it is a known complication is saying that it's the same kind of thing that happened with the permanent filters. But it's not. And to say there's been some reports of serious pulmonary and cardiac complication grossly understates the potential risk here of a patient dying 10:29:35 from this device.

And finally, you know, the way that this is worded saying "requiring the retrieval of the fragment using endovascular surgical techniques," that makes it sound like this is really easy to do, to go get one of these fragments, 10:29:54 when it's not. And it makes it sound like it always happens,

like you're always able to retrieve it, it's never a problem.

So, you know, I think this just grossly understates the severity of the issue here.

THE COURT: Mr. Combs, we're at 10:30.

So we're going to break for 15 minutes, ladies and gentlemen. We'll excuse you at this time.

(The jury exited the courtroom at 10:30.)

THE COURT: All right. See you in 15 minutes.

(Recess taken from 10:30 to 10:42. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

Counsel, let me tell you where I am now on the issue that was raised by you this morning, Ms. Helm.

The -- I haven't read the two cases; my law clerk has. They were both cited in our motion in limine ruling, so we've seen them before. And I was reacquainted by my law clerk with them, having read them before.

We're going to confirm this in the transcript, but plaintiff has withdrawn, I believe, any damages based on life expectancy, shortness of breath, weakness, which addressed smoking and anemia; is that correct?

MR. COMBS: That's correct, Your Honor. Yes.

THE COURT: What I want to do, not while we're keeping the jury waiting, is tie down exactly the categories of damages plaintiff is seeking.

10:44:18 There is something I haven't done yet, which is go back and reread the opening and the pain and suffering and the worry references, which I will do.

But at this point I'm not persuaded that the
10:44:33 plaintiff has opened the door to Ms. Jones' other medical conditions, so for purposes of cross-examination that shouldn't be addressed.

I do want to look more closely at the transcript. I will hear further arguments from the parties.

10:44:46 If I decide at some point the door's open, Ms. Jones will certainly be available to recall during the defense case. But at this point I'm not persuaded the door is opened, having been reminded what those cases say and having thought about it while I was up here.

10:45:04 So going forward this morning, we shouldn't be going into those areas. We'll come back to that subject.

Okay, let's bring the jury in.

(The jury entered the courtroom at 10:45.)

THE COURT: Please be seated.

10:46:48 You may continue, Mr. Combs.

MR. COMBS: Thank you, Your Honor.

BY MR. COMBS:

Q Dr. Hurst, to wrap up on the IFU, or instructions for use, for the Eclipse filter, if Bard had information that its
10:47:01 Eclipse filter had increased rates of failure compared to

10:47:05 other filters, including its own Simon Nitinol filter, is that something that you and the medical community would expect to see in the IFU?

A Yes.

10:47:14 Q Is that information in the IFU?

A No.

Q And I apologize, I'm probably going to jump around a little bit here to finish up.

According to Dr. Avino's records, where was the

10:47:30 filter placed?

A At the -- the tip of the filter was positioned at the L1-L2 disk level.

Q And then exactly what failure modes did it subsequently have?

10:47:47 A So the filter went on to tilt in the inferior vena cava and then it fractured. I'm sorry. The filter first caudally migrated, which means it settled, and then it tilted and then it fractured. And the fracture fragment embolized to the right pulmonary artery.

10:48:07 Q So Mrs. Jones' filter suffered migration, tilt, and fracture?

A Yes, sir.

Q Dr. Hurst, is reviewing medical literature part of your practice?

10:48:25 A Yes.

10:48:25 Q Why is that important for a physician like yourself?
A Well, we review medical literature because that's the way we get the information on new procedures, old procedures, devices. It's just basically part of our practice.
10:48:41 Q And what medical literature did you review for this case?
A I reviewed over 100 articles that were -- that I found on Medline and in our own journals in regards to all types of IVC filters, including the Bard filters.
Q Are there a lot of articles about IVC filters?
10:49:02 A Prior to 2002 there were probably only 70 articles in the literature. After 2002 there were over 2- or 300.
Q Did some of the medical literature you review focus specifically on Bard Is IVC filters?
A Yes.
10:49:22 Q Did those -- did you review those articles?
A Yes, I did review those articles.
Q And did those articles support the opinions you've given today?
A Yes, they do.
10:49:35 Q Okay.
MR. COMBS: Gay, if you could please pull up Exhibit 932.
BY MR. COMBS:
Q And what is Exhibit 932, Dr. Hurst?
10:49:48 A This looks like a Bard corporate document.

10:49:53 Q Is this a document that you reviewed and relied on in creating your report, formulating your opinions in this case?
A Yes, I did review this document.
MR. COMBS: Your Honor, I'm not entirely sure if this
10:50:05 is in evidence or not, but I'll move into evidence if it's not.
MR. ROGERS: No objection.
THE COURT: Admitted.
(Exhibit 932 admitted.)
10:50:14 MR. COMBS: May I publish to the jury?
THE COURT: Yes.
MR. COMBS: If you could please, Gay, go to page 6.
BY MR. COMBS:
Q And, Dr. Hurst, is this a type of document that physicians
10:50:28 would ever see?
A No.
Q And do you see there on the right column, the bullet points under "Weaknesses"?
A Yes, I do.
10:50:42 Q And do you see the second bullet point down there?
A Yes.
Q What does that say? If you could please read it to the jury.
A Yes. "Lack of thorough understanding of the dynamics of
10:50:52 caval anatomy."

10:51:00 Q Would it be a reasonable expectation of interventional radiologists like yourself that a medical device company would have a thorough understanding of the anatomy of the area where a medical device would be permanently implanted?

10:51:14 A This would be part of the due diligence that we discussed before.

Q And why is understanding the dynamics of the caval anatomy particularly important to the manufacturer of an IVC filter?

A Because the IVC -- I'm sorry. The inferior vena cava is

10:51:29 what we call a hostile vascular environment. It's under constant stress. It can change rapidly in diameter related to the patient's blood volume. It can collapse almost completely. It can expand quite a bit. It can also stretch, move sideways, with every movement of the body.

10:51:53 Q If a medical device manufacturer lacked an understanding of the anatomy of the area where a medical device is going to be implanted, what would you expect -- reasonably expect it to do before it placed that on the market?

A I would expect it to have a testing method that would

10:52:11 allow it to understand the anatomy, understand the dynamics of that IVC.

Q Let me put it a different way. You would reasonably expect that a medical device manufacturer would understand the dynamics of the anatomy before they would put a medical device

10:52:33 out on the market for placement in that anatomy?

10:52:37 A Yes.

MR. COMBS: Gay, move on to 991.

And just the top.

I'm sorry, Your Honor. I believe this is in evidence

10:52:51 also.

THE COURT: Yes.

MR. COMBS: Can I publish to the jury?

THE COURT: You may.

BY MR. COMBS:

10:53:00 Q Dr. Hurst, is this a document that you reviewed and relied on for your report?

A Yes.

Q And this -- this appears to be an e-mail from a David Ciavarella to several people dated 12/27/05.

10:53:22 I'll represent to you that David Ciavarella was the medical director for Bard at the time.

MR. COMBS: I want to focus on the last four paragraphs, if you could zoom in on those, Gay.

BY MR. COMBS:

10:53:33 Q And do you see there kind of in the middle of the page, it starts with "I would like to look more generally at the G2 complaints. I have seen problems with caudal migration, tilting, perforation, misdeployment, and maybe one or two additional things."

10:53:51 Do you see that?

10:53:52 A Yes.
Q If internally Bard was aware of problems with the G2 in 2005, would interventional radiologists like yourself have expected -- reasonably expected Bard to share that
10:54:05 information?
A If they had information that would be helpful to us, yes.
Q And let's go down to the paragraph there that starts with the G2.
It reads: "The G2 is a permanent filter. We also
10:54:23 have one, the SNF, that has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2?"
Do you see that, Doctor?
A Yes, I do.
10:54:35 Q If Bard believed the SNF was a safer permanent filter than the G2 filter, is that information that would have been important to you as an interventional radiologist implanting the G2 line of filters in your patients?
A Yes.
10:55:01 MR. COMBS: Let's go to the next one, Gay. It's going to be 2248.
BY MR. COMBS:
Q Before I get into this one specifically, you reviewed a lot of Bard documents in this case; right?
10:55:22 A Yes.

10:55:23 Q And Bard deposed you in this case; right?
A Yes.
Q Has Bard ever shown you any documents that have put any of these documents you've reviewed in context, in a different
10:55:36 context, or challenged you to change or question your opinions?
A No.
MR. COMBS: Let's go to page 20, Gay, please.
And I believe this is in evidence also, Your Honor.
10:55:52 THE COURT: It is.
MR. COMBS: May I publish to the jury?
THE COURT: Yes.
BY MR. COMBS:
Q And, Doctor, this is another document that you reviewed
10:56:04 and relied on in formulating your reports; correct?
A Yes.
Q And do you see there where it describes where it's been highlighted that Bard internal analysis determined that the G2 filter had an unacceptable risk of caudal migration?
10:56:22 A Yes.
Q If Bard determined internally that its G2 line of filters posed an unacceptable risk of caudal migration, was that information that you and other interventional radiologists would have reasonably been expected to have been told?
10:56:37 A Yes.

10:56:38 Q Was that ever told to you?
A No.
Q Was it in the IFU?
A No.
10:56:46 Q Do you test medical devices?
A No.
Q Do you design medical devices?
A No.
Q And how do doctors like yourself, how do they learn about
10:56:56 medical devices?
A There's several different ways to learn. We get information from the device manufacturer. There are training -- sometimes training programs supplied by the device manufacturer, sometimes the training programs are performed by
10:57:14 our own society. And following release of the device, or even before release of the device, usually there are studies that are done that are published in our major journals so that we can learn about the device.
Q You're a busy physician; right?
10:57:31 A Yes.
Q And you have to rely on medical device companies to tell you things about their devices.
A It's a back and forth. Yes.
Q If a -- if there's important information about a medical
10:57:47 device and a manufacturer doesn't tell anyone, how does the

10:57:51 medical community ever learn about that issue with the device?
A Well, usually what happens is there will be a series of case reports where physicians who have experienced some sort of adverse event have published a report in a journal. Then
10:58:08 sometimes that will snowball into discussions at local or national meetings. And then there will be usually some sort of incentive to do a trial of some sort to further evaluate the device if it's having issues.
MR. COMBS: Sorry, I had one more question about
10:58:35 2248, if I could publish it again.
May I publish?
Thank you.
BY MR. COMBS:
Q This document and other Bard documents dealt with the G2
10:58:58 filter; right?
A Correct.
Q And were there any design changes between the G2 and Eclipse filters to improve caudal migration?
A No.
10:59:13 Q What was the model of Bard IVC retrievable filter after Eclipse?
A The Meridian.
Q And what were the -- what's the difference between the Eclipse and the Meridian?
10:59:26 A So the Meridian put what are called caudal anchors on the

10:59:31 arms of the filter, and these were little feet that were kind of turned upside down on the arms so that when the arms interacted with the wall of the inferior vena cava it sort of held it in place and kept it from migrating towards the feet.

10:59:48 MR. COMBS: And, Gay, if we could pull up now Exhibit 2238, please.

I'm not 100 percent sure, Your Honor, but I believe it's been moved into evidence.

MR. ROGERS: Your Honor, I'm standing up to object 11:00:11 because I don't believe this document has ever been discussed in any of Dr. Hurst's reports or prior testimony.

THE COURT: It's not in?

THE COURTROOM DEPUTY: It's not in.

MR. COMBS: My response, Your Honor, is I'm positive 11:00:42 it's on his reliance list and he's disclosed extensive opinions about the Meridian versus the Eclipse.

THE COURT: Can you show me where it is on the reliance list?

MR. COMBS: Let me find it.

11:01:00 It's number 20, which is page 14. And I can give you --

THE COURT: That is 2238?

MR. COMBS: Yes.

THE COURT: And where is it in the opinion?

11:01:19 MR. COMBS: Page 9 at the bottom it starts, and then

much of the paragraph that goes most of page 10 discusses the Meridian as well.

THE COURT: Is there any discussion in the report of Exhibit 2238?

MR. COMBS: I don't believe specifically, Your Honor, no.

THE COURT: Objection is sustained.

MR. COMBS: Thank you, Your Honor.

BY MR. COMBS:

Q If Bard believes, Dr. Hurst, that its IVC filters needed improvements to improve safety, is that information doctors like you would have reasonably expected to know?

A Yes.

Q Does the warning on migrations in the IFU that we reviewed say anything about Bard having unacceptable risk of caudal migration?

A No.

Q Does the warning on filter fractures say anything about migrations causing fracture?

A No.

Q The opinions you told the jury today -- told the jury about today to a reasonable degree of medical probability?

A Yes.

MR. COMBS: Nothing further at this time, Your Honor.

THE COURT: All right.

Cross-examination?

MR. ROGERS: Yes, Your Honor.

C R O S S - E X A M I N A T I O N

BY MR. ROGERS:

Q Good morning, Dr. Hurst.

A Good morning.

Q I don't believe you and I have had a chance to meet.

A We have not.

Q Doctor, I want to first ask you some questions about your experience as an expert witness.

A Sure.

Q Am I correct that you first started doing expert witness work in 2014?

A Yes.

Q And, Doctor, am I correct that the majority of the cases in which you have been retained as an expert have been in medical malpractice cases?

A Yes.

Q Am I correct that since 2014 you have been retained as an expert in at least 20 medical malpractice cases?

A Yes.

Q And, Doctor, am I correct that of those 20 or so medical malpractice cases where you have been retained as an expert, that you have been retained as an expert by an attorney representing the plaintiff in all but two of those cases?

11:04:38 A Yes.
Q And, Doctor, am I correct that you have formed a business for your expert witness work?
A Correct.
11:04:47 Q And what is the name of that business?
A Tristate Medical Legal Consulting.
Q Is the Tristate because you're licensed in Indiana, Kentucky, and Ohio?
A Yeah.
11:04:58 Q Am I correct, though, Doctor, that the only state in which you actually perform procedures is in Kentucky?
A That's because our hospitals are in Kentucky, yes. But I read images from all three states.
Q I see. But the procedures you perform are just in
11:05:13 Kentucky?
A Currently yes. We'll have a hospital in Indiana where we'll be doing procedures in about six months.
Q Doctor, do you have a LinkedIn page?
A Yes.
11:05:22 Q And is the Tristate Medical Legal Consulting business you have featured on your LinkedIn page?
A I wouldn't say it's featured. It's on there. It's listed --
Q It does --
11:05:35 A Yeah, it does appear.

11:05:36 Q Thank you, Doctor.

And, Doctor, do you list yourself on certain websites that are referral services for expert witnesses for lawyers who are looking for experts?

11:05:46 A That one website, S-E-A-K, yes. Seak.

Q S-E-A-K. That's the Seak website?

A (Nods head.)

Q And, Doctor, have you ever looked at a website called the LexVisio website?

11:05:58 A No.

Q And would you be surprised to know you appear on that website as a potential expert?

A Sure. Yeah.

Q And you didn't do anything to put yourself on that

11:06:07 website?

A No, I did not.

Q And the Seak website that you were talking about, am I correct that you pay an annual fee to have a listing on that website?

11:06:14 A I do.

Q And what is that fee, Doctor?

A It's 600 bucks.

Q And does that cover all of your listings that you have on there?

11:06:23 A Yes. Yeah.

11:06:25 Q And, Doctor, the Seak company that has this website, does it also offer classes for individuals who want to be expert witnesses or for expert witnesses who want to become a better expert?
11:06:41 A Yes.
Q And have you ever taken advantage of any of those classes?
A I have not.
Q Does the Seak company also offer books and DVDs so that people can purchase those in order to learn how to be a better
11:06:54 expert?
A Yes.
Q Have you ever purchased any of those?
A Yes.
Q Do you recall the name of anything you purchased?
11:07:01 A I think it was how to start an expert witness business. I'm not sure what the title was.
Q Was it a book or video?
A It's a book.
Q Is that the only thing you've ever purchased?
11:07:15 A Yes.
Q And, Doctor, the listing that appears on the Seak website, is that something that you wrote yourself?
A Yes.
Q And did you want to put everything that you felt like was
11:07:25 important for lawyers who were looking for experts in that

11:07:29 listing?
A Yeah.
Q And, Doctor, am I correct that one of the areas of expertise that you list in the Seak website is expertise in
11:07:39 IVC filter product liability cases?
A Yes.
Q And you wrote that?
A Yes.
Q You felt like it was important for the community of
11:07:48 lawyers who may be looking for an expert witness to know that is an area of your expertise?
A Sure.
Q Doctor, the case we're here for today is a IVC product liability case; correct?
11:07:58 A Yes.
Q Doctor, let me shift gears and talk to you a little bit about your experience with IVC filters.
Am I correct that only about 5 percent of your time is spent with either implanting or retrieving IVC filters?
11:08:16 A 5 percent of my time. I'd say it is probably more like 10 percent.
Q Okay. So if you testified previously that the percentage of your practice of placement and retrieval of IVC filters is only 5 percent, you wouldn't disagree with that, would you?
11:08:34 A Well, I did testify to that, but the number of retrievals

11:08:37 has gone up.
Q And, Doctor, you've never published anything in the peer-reviewed medical literature about IVC filters, have you?
A I have not. I'm a private practice physician, so I don't
11:08:46 do that type of research.
Q And I take it you've never published any book chapters about IVC filters?
A I do not. Have not.
Q And, Doctor, are you a member of an organization called
11:08:56 the Society of Interventional Radiologists?
A Yes, I am.
Q And is that the national society for people who are in your profession?
A Yes.
11:09:05 Q And do you ever attend meetings of the Society of Interventional Radiologists?
A I do.
Q Does it have an annual meeting?
A Yes.
11:09:12 Q And have you ever given any presentations at that meeting to other interventional radiologists about IVC filters?
A I have not.
Q And, Doctor, within the Society of Interventional Radiologists, is there something you can become called a
11:09:25 fellow?

11:09:27 A Yes.
Q And can you tell the jury, please, what that is.
A So to get -- to become a fellow of the Society of Interventional Radiology you need to publish, usually it's an
11:09:38 academic -- you have to be in an academic institution. You need to have, I think, two supporting references. I think that's it.
Q And so as I understand it, you say it's limited to just people who are in academic institutions?
11:09:58 A It's not limited to that, but predominantly it is people who are in academics.
Q Am I right that only about 5 percent of those members of that society have been deemed fellows?
A Yeah, they have applied for it. Yes.
11:10:10 Q Doctor, have you ever been through that vetting process to become a fellow?
A I never felt like it was necessary.
Q Doctor, let me switch gears again and ask you a little bit about your experience with Bard IVC filters.
11:10:23 I think you got asked a question during the direct examination about your current use of filters. And am I right you currently do place a Bard IVC filter called the Denali filter?
A Yes, we do.
11:10:40 Q Doctor, as I understand it, before you got involved in

this litigation you routinely used Bard filters. Is that true?

A Yes.

Q Once you were retained as an expert, am I also correct that based on some of the documents that you reviewed, that you decided that you would stop using Bard filters?

A Except for the Denali, yes.

Q Okay. So you never completely quit using Bard filters altogether?

A No. And part of that has to do with the product that we have at certain hospitals.

Q Okay. And, so, Doctor, am I correct that some of your concern that you had about the use of IVC filters that were manufactured by Bard was because of what you had seen in some of the documents that you -- about -- that had been produced by Bard; correct?

A Yes.

Q And am I right, Doctor, that when you made this decision about whether you would continue to use Bard filters, that you had only seen about 20 documents that had been produced by Bard?

A Well, I don't think it really had to do as much with the documents by Bard. It had to do with what was happening in our society and in the medical literature and some of the issues that my colleagues would have with devices.

11:11:49 We had a fracture migration, we had a full filter migration, we had penetrations, things that -- patients where we had to retrieve devices and pieces of devices. So it was our personal experience as a group.

11:12:03 We have seven interventional radiologists. We have a very busy practice, very busy hospital, and also we're connected to the other practices in town and in our region, and we discuss things like that. So when it came to the Bard filters, especially the G2, Recovery era of filters, well, the

11:12:25 Recovery was actually taken off the market before any of this occurred in my life, but -- and the G2 was probably gone at that point too. So the only device we stopped using, really, was the Meridian. And we moved to the Denali because the Meridian was actually discontinued as well, so we were left

11:12:45 with the Denali filter. And we changed our practice. We no longer leave those filters in permanently. Every patient is followed and their filter is either removed at three months or we -- if they need a permanent filter, we remove their filter and put in a permanent filter, usually a VenaTech filter.

11:13:07 Q Are you finished, Doctor?

A Yes. I'm sorry. I just wanted to qualify that statement. That's why we use the filter right now --

Q I did understand. But we're clear that you do currently implant a Bard filter called the Denali filter?

11:13:19 A We do, yes.

Q And that is a conical filter as you described previously --

A Yes.

THE COURT: Excuse me.

Counsel and Doctor, we're talking over each other. It's very hard for her to take down, so let's kind of pause, please, between questions and answers.

MR. ROGERS: Absolutely, Your Honor.

THE WITNESS: We use it as a retrievable-only filter, yes.

BY MR. ROGERS:

Q Doctor, to get back to the documents you reviewed, am I correct when you formed your opinions in this case that you had looked at only about 20 Bard documents?

A I'd actually looked at probably more than that, but those are the 20 that are included in there. I've reviewed a case, separate case, where we reviewed even more Bard documents than that.

Q And when you wrote your opinions in this case and put down all the things you relied on for this case, you only listed about 20 documents; right?

A Yes.

Q And, Doctor, am I correct that after you wrote your opinions in this case that you were provided with an electronic drop box that contained many more Bard documents;

is that right?

A That is correct, yes.

Q But you've never gone and looked through anything in that electronic drop box, have you?

A Oh, I certainly have, yes.

Q You have?

A Absolutely.

Q And, Doctor, have you testified previously that you had not looked through that drop box?

A I may have at that point, but certainly -- there's over a million documents in this case, so there are times when I've gone back to that drop box to look for something to answer a question.

Q And when was this review of the materials that was in the drop box?

A I can't say. I'm sure it was within the last couple of months.

Q Okay. So it was immediately before this trial; is that correct?

A No. Actually, it was probably before the Booker trial. A separate trial.

MR. ROGERS: And, Your Honor -- well, let me continue.

BY MR. ROGERS:

Q So just so we understand, so for your opinions in this

11:15:15 case, you only looked at about 20 documents; right?
A 20 Bard internal corporate documents? Probably, yes.
Q Even though you looked at those 20 documents, you continued to implant the Bard Denali filter. True?
11:15:30 A Those documents aren't in regard to the Bard Denali filter, but yes.
Q But those documents are about Bard; right?
A Sure. Yeah.
Q And, Doctor, you have implanted Denali filters in calendar
11:15:42 year 2018. True?
A Yeah, Um-hmm.
Q Can you tell us when the last time you implanted a Bard Denali filter was?
A Probably about four weeks ago, I would say.
11:15:53 Q And do all the facilities where you practice stock Bard Denali filters?
A They currently do, yes.
Q And I believe you testified earlier that you were on something called a product committee; is that correct?
11:16:05 A Yes.
Q And so has that Bard filter made it through the product committee so it's in use at your hospitals?
A Yeah. Actually, we evaluated that device in comparison to the other retrievable filters that are available. And even
11:16:19 though it has weaknesses, as we discussed, the weaknesses that

the prior devices had have been somewhat mitigated by the changes that they made over time through the family of filters.

So when they started with these filters, they had lots of issues. And during each iteration of the filter, they addressed the issues one by one by one by one.

They're still not perfect and we still have issues with the retrievable filters, but now that we take them out and we don't use them as a permanent filter, we have much less problems because those issues tend to occur over time and the risk tends to increase over time.

Q And, Doctor, am I correct that there is no such thing as a perfect filter?

A There is no such thing as a perfect filter.

Q And just to finish this line of questioning about documents, am I correct that you have never seen any internal documents from any other filter manufacturer besides Bard?

A I have not.

Q So you don't have any idea what's in any internal documents of any other company that manufactures IVC filters. True?

A True.

Q And, Doctor, you also currently use a filter called the Gunther Tulip; is that right?

A Yes.

11:17:32 Q And you use a filter called the VenaTech filter?
A Correct.
Q And you've never seen any documents that those companies that make those two filters have produced that are their
11:17:41 internal documents; is that right?
A No, we do not receive internal documents.
Q All right. Let me pick up about no filter being perfect. And, Doctor, would you agree that all IVC filters have risks?
A Yes. I've already said that.
11:17:54 Q And would you agree all IVC filters can fracture?
A All IVC filters can fracture, but this particular filter fractures and embolizes.
Q So, Doctor, is it your testimony that if another filter fractures, there's no way that it can embolize; is that
11:18:09 correct?
A In the permanent filter world there were no fractures that embolized. So the permanent devices, there are no reports of an embolization of a fracture fragment.
Q Well, Doctor, would you agree that all retrievable filters
11:18:25 have the potential for fracture and migration of a piece of the filter that breaks off?
A The current retrievable devices? Yes, they all have that risk.
Q And would you agree all IVC filters can perforate or
11:18:39 penetrate the walls of the IVC?

11:18:41 A Yes.
Q And would you agree that all IVC filters have the potential for migration?
A You would have to tell me what kind of migration you're
11:18:50 discussing.
Q Well, do you agree all IVC filters have the potential to caudally migrate?
A Not to the degree that these filters do.
Q Do you agree all retrievable filters have the potential to
11:19:04 caudally migrate?
A The OptEase doesn't really caudally migrate, but, yeah, the Gunther Tulip and this filter do because they're conical filters. It's their design.
Q And would you agree that all retrievable filters have
11:19:18 potential to tilt?
A No. The OptEase filter, because of its design, can't tilt. The Gunther Tulip definitely tilts, it's a conical filter of similar design to this device. So the two conical filters, yes, they both have the propensity to tilt. They
11:19:40 both have similar problems.
Q And, Doctor, am I right that many, many models of filters that are on the market today have the potential to tilt?
A Do you mean permanent or retrievable filters?
Q Retrievable filters.
11:19:52 A Well, we've already discussed -- there's only four, I

11:19:54 think, retrievable filters on the market. Five. So the conical ones, the ALN, the Bard filters, and the Gunther Tulip filters all have the propensity to tilt. OptEase, which is not a conical style filter, does not. And the VenaTech, the 11:20:11 new VenaTech convertible filter does not.

Q And, Doctor, do you implant these filters in patients that have a potential to fracture even though you know that there's that potential?

A We didn't know that there was such a potential when we 11:20:28 were placing the Recovery, the G2, the G2X, and the Eclipse. The Denali, I hope, will not have the issues of fracture because I hope that it's not going to caudally migrate and start the cascade of events that causes fracture.

Q And, Doctor, let me ask you about that term, "cascade of 11:20:50 events." You've used that several times during your testimony; correct?

A Um-hmm.

Q Have you ever seen that term used in the medical literature?

11:20:58 A I'm not sure I've seen the term used, but the cascade has been described in the medical literature, yes.

Q But not in the terms of using "cascade"; is that correct?

A No, I guess -- I'm not sure. I've never seen it used, but yes.

11:21:14 Q Have you ever been to a medical meeting where another

11:21:17 doctor described a cascade of events in regard to IVC filters?
A Not using that terminology.
Q And have you ever heard this term "cascade of events" in regard to IVC filters outside of the context of litigation?
11:21:31 A No.
Q And, Doctor, when you implant an IVC filter, is it because you are doing it to provide a benefit to your patient, or potential benefit?
A Yes.
11:21:44 Q And is that benefit to potentially save the patient's life in case they've got a high risk for a pulmonary embolism?
A Yes.
Q And, Doctor, you talked some in your direct examination about the informed consent process. Do you remember that?
11:22:00 A I do.
Q And when you are treating your patients, do you go through a standard informed consent process with your patients who are going to receive an IVC filter?
A Yes.
11:22:12 Q And, Doctor, as part of that process, do you tell your patients about the potential risk of fracture, tilt, migration, and perforation?
A We used to. I'm not sure I really discuss fracture, tilt, migration, and perforation as much anymore because we really
11:22:28 don't see it as much with the Denali device.

11:22:31 Q So you don't talk to your patients about that currently?
A I tell them there's a small risk of those types of complications occurring, but -- yeah, I guess we still do tell them about those risks.
11:22:43 Q And do you tell your patients there's a risk of serious injury or death in regard to an IVC filter?
A I usually don't, actually. That scares them.
MR. ROGERS: Can we pull up Dr. Hurst's deposition testimony from his deposition in this case, please.
11:23:16 And specifically I'm looking for page 37, line 8.
BY MR. ROGERS:
Q And, Doctor, do you see your testimony from this deposition?
A Yes.
11:23:33 Q And, Doctor, am I correct that the question you were asked -- let me back up for a moment.
This deposition was taken in 2017; is that right?
A Yeah.
Q And, Doctor, when you were asked these questions, you were
11:23:48 under oath, just as you're under oath today. True?
A Yes.
Q And you wanted to provide the most truthful and accurate testimony you could; correct?
A Yes.
11:23:56 Q And, Doctor, on that date you were asked the question,

"When you implant a filter, do you specifically advise the patient that the filter has the potential to fracture?"

A Correct.

Q And your response was, "I advise the patient that there is a risk of fracture, migration, malfunction," it says "cable occlusion. We basically have a standard consent form."

Did I read that correctly?

A You did.

MR. ROGERS: And if we could also, before we move on, go on to page 38, line 18. Would you pull that back up, please.

BY MR. ROGERS:

Q And, Doctor, here the question is -- do you see that?

A Yeah.

Q The question is, "Do you specifically write in 'penetration'?"

And that's in regard to the specific consent form the patient signs; correct?

A Correct.

Q Your answer is, "Yes, I do write there's a risk of penetration and cable occlusion and death."

Did I read that correctly?

A Yeah. So basically the consent form is a standard consent form that has all of these complications there. When I said I write in, basically that is already on the consent form.

11:25:25 With every patient you have to judge what you're going to discuss with them or not. There are some patients who don't want to know anything and, in fact, they will tell you right up-front, I don't want to know anything, Doc, just
11:25:36 put it in, I trust you.

There are other patients who want to know every single detail, everything you could possibly tell them. And so then you sit down and you have a discussion about every single possible complication.

11:25:50 So it varies what we tell the patients. So --

Q And --

A Sorry. The legal form that is given to the patient has all of these things listed. It varies what we tell the patients. So, yes, I said this, and now I'm telling you what
11:26:09 we really do.

Q And so you would agree your testimony today is different than what you testified to in your deposition?

A Yeah, it's different.

Q Doctor, would you agree that all medical devices can be
11:26:23 made safer?

A Sure.

Q And is that true for IVC filters?

A Yes. We're continually looking for ways to make them better.

11:26:32 Q And you certainly recognize that there's no such thing as

11:26:35 a risk-free medical device; is that right?

A There is no such thing as a risk-free medical device. That is true.

Q Doctor, you testified today about what you consider to be 11:26:49 acceptable rates of complications for filters. Do you recall that?

A I do.

Q And do you recall your testimony that you thought that if it was a particularly serious outcome, you thought that a risk 11:26:59 of one out of a million was an acceptable rate. Do you recall that?

A Catastrophic. Yes.

Q Catastrophic. That's the word you used.

A Yes, that's the word I used.

11:27:09 Q Would you agree, Doctor, in order to measure whether or not that standard can be satisfied, there has to be at least a million of the filters that are out there in patients; is that true?

A No. That's not the way statistics works.

11:27:25 Q Okay. Doctor, would you agree with me that previously you had testified that you felt like if an IVC filter had a complication rate of less than 1 percent, that that would be an acceptable rate?

A I did testify to that, yes.

11:27:39 I'm sorry, you said complication rate?

Q Yes.
A Can you repeat that, that question?
Q Sure, I'm glad to.
Have you previously testified that if a IVC filter has a fracture rate of less than 1 percent that would be an acceptable rate?
A That's true. With the permanent devices, when they fracture, like I said before, because there's two attachment points, it was an event that you could put up with, that you could tolerate. But if you're talking about fracture with embolization, no.
Q And you never offered any of those kind of qualifications in your prior testimony, is that correct, Doctor?
A I did not.
Q Doctor, would you agree with me also you have previously testified that if an IVC filter has a migration rate of less than 1 percent that that would be an acceptable rate?
A I did.
Q And did you also testify that if there is a tilt rate of less than 1 percent that that would be acceptable?
A I did.
Q Doctor, let's change gears and talk a little bit about your specific opinions about Mrs. Jones.
And you testified earlier that Mrs. Jones was an appropriate patient for an IVC filter; correct?

11:28:53 A Yes.
Q And is that because she had very severe bleeding ulcers at the time she got her filter?
A She had contraindication to anticoagulation and had a DVT.
11:29:08 Q Okay. So at the time she got her filter she had active bleeding but she also had a blood clot in her legs; is that correct?
A That's correct.
Q She could not take an anticoagulant or blood thinner
11:29:18 because she had active bleeding and also needed to have surgery to try to treat the bleeding ulcers; correct?
A Yes, sir.
Q So had Ms. Jones been your patient, you would have put an IVC filter in her; is that right?
11:29:32 A Yes.
Q And, Doctor, when you were testifying earlier, do you recall talking about how medical device companies need to do due diligence?
A Yes.
11:29:42 Q And would you agree with me that that applies to medical professionals as well?
A Correct. Yeah.
Q And do you think it's important for a doctor to engage in due diligence before the doctor makes a diagnosis or treats
11:29:54 the patient?

11:29:55 A Absolutely. You want all the information you can possibly have before you make a decision.
Q And so you think you -- you would agree with me that it's important for a doctor to review all important records about a
11:30:05 patient before they engage in the care of that patient?
A Yes.
Q And that's part of the due diligence process for a medical doctor; right?
A Well, I mean, it depends. Sometimes you're brought in as
11:30:19 a consultant and you're only asked to review a specific portion of the patient's medical care. So obviously I'm not involved in treating a patient's skin condition or things like that. So I'm not going to review all of the patient's medical records before I place an IVC filter. I'm going to review the
11:30:38 pertinent medical records.
Q As a medical consultant in this case serving as an expert witness, do you think it was important for you to review all the important records that relate to Doris Jones?
A The pertinent medical records, yes.
11:30:50 Q And, Doctor, I don't believe you reviewed any records of Mrs. Jones that existed prior to 2009; is that right?
A Correct.
Q And so, Doctor, if Mrs. Jones had previously been diagnosed with other episodes of gastrointestinal bleeding and
11:31:09 that she had a previous DVT, is that information you were

11:31:13 aware of?
A No.
Q So none of those medical records were provided to you by plaintiff's counsel. Is that true?
11:31:19 A No.
Q And you haven't had an opportunity to review those records; correct?
A No.
Q And, Doctor, at the time you issued your report in this
11:31:26 case, am I correct that you had not reviewed the images from the implantation of the filter in Mrs. Jones; is that right?
A I requested them, but they did not have them.
Q And is the same true for the explantation films when Mrs. Jones' filter was removed?
11:31:46 A Again, I requested them, but they did not have them.
Q And, Doctor, am I also correct you have reviewed no medical records that relate to Mrs. Jones after her filter was removed in 2015?
A That's correct because it's not pertinent to my testimony.
11:32:07 Q I see. And so if there's any information in her medical records from a hospitalization in 2016, you have not had a chance to review those records; is that right?
A I actually have reviewed those records because you gave them to us.
11:32:20 Q Okay. And, Doctor, am I correct, though, that there's

11:32:24 imaging from that hospitalization of Mrs. Jones' lung in 2016?
A Correct. There is.
Q And, Doctor, when you issued your report in this case, you had not reviewed that imaging, which would be the most recent
11:32:38 imaging of this strut in Mrs. Jones' lung; correct?
A Correct.
Q Now, Doctor, let's talk a little bit more about Mrs. Jones and some of the opinions that you did give.
And you would agree with me that Mrs. Jones got her
11:32:54 Eclipse filter in 2010; right?
A Yes.
Q And I also don't believe you reviewed the deposition testimony of Dr. Avino, who put in the IVC filter?
A I did review that.
11:33:05 Q You did. But that wasn't disclosed in the information in your report; is that correct?
A I guess it wasn't.
Q And so you had a chance to review Dr. Avino's testimony regarding what he was using Mrs. Jones' filter for as to
11:33:21 whether or not it was permanent or retrievable; right?
A Correct.
Q And I think you testified in your direct exam that you considered this filter to have failed as a permanent filter; right?
11:33:31 A Yes.

11:33:32 Q And if Dr. Avino wanted this filter to be a retrievable filter, would that change your opinion?
A No. It still failed because the device fractured and deteriorated.
11:33:44 Q So it really doesn't matter to you if it was a retrievable filter or permanent filter; is that right?
A It still failed.
Q And, Doctor, at the time you wrote your report in this case, I also don't believe you were provided any medical
11:33:59 records for a hospital admission that Mrs. Jones had in 2009; is that right?
A I'm not sure about that one.
Q Well, if it's not in your report, would you agree with me that you didn't review them?
11:34:12 A I might have reviewed it, but I may not have found it pertinent. But go ahead.
Q Okay.
MR. ROGERS: Can you put up 8067, please.
BY MR. ROGERS:
11:34:20 Q And, Doctor, can you see this exhibit on your screen?
A I can.
Q And can you see there that it a history and physical that was taken of Mrs. Jones in January of 2012?
A Yes.
11:34:38 MR. ROGERS: And, Your Honor, I move for admission of

11:34:39 this record into evidence.

MR. COMBS: Objection, Your Honor. Motion in limine. Relevancy.

THE COURT: I don't know what you mean by motion in

11:34:51 limine. Let's talk for a minute.

If you want to stand up, ladies and gentlemen, feel free.

(Bench conference as follows:)

THE COURT: What are you referring to, Mr. Combs?

11:35:19 MR. COMBS: Objecting on relevance. I believe this is part -- you limited in your motion in limine rulings just to talking about anemia as far as past medical --

THE COURT: Other medical conditions. I agree. But that's what -- so you think this exhibit touches on that?

11:35:35 MR. COMBS: Correct.

THE COURT: Mr. Rogers?

MR. ROGERS: The reason I want to use that exhibit is Dr. Hurst has testified that when she presented in 2015 she had chest pain, and in this particular admission she also

11:35:45 presented with chest pain. And I think that those admissions where she has the similar complaints to what she had when she presented in 2015 are very relevant and important for us to read here.

THE COURT: Well, is there other material in there

11:36:00 about anemia or other medical conditions?

11:36:03 MR. ROGERS: We have redacted, have we not, the other conditions, Your Honor.

THE COURT: Have you seen the redacted version?

MR. COMBS: I believe my colleagues have reviewed the 11:36:14 redacted version. I haven't personally.

THE COURT: So you're moving in the redacted version?

MR. ROGERS: Yes, Your Honor.

THE COURT: And you think your team has reviewed that and approved it?

11:36:22 MR. COMBS: I do, Your Honor.

THE COURT: So if the other medical conditions are redacted, what's your objection?

MR. COMBS: I think it's still lack of relevance. They don't have anybody that's going to come in and say this 11:36:31 was chest pain -- I mean, they haven't disclosed any opinions from anybody that's going to link this chest pain to anything else related to her filter or say it was the same as the pain she was having in 2015. So it's really just inviting the jury to speculate about irrelevant stuff.

11:36:48 THE COURT: Before I hear his response, my understanding is you are claiming physical pain related to the filter as a category of damages in the case.

MR. COMBS: Yeah. Pain and suffering in that window of when she came into the ER and had it removed. That's the 11:37:05 pain and suffering --

11:37:06 THE COURT: So you're going to be asserting to the jury that the pain and suffering she was experiencing was caused by the filter?

MR. COMBS: Your Honor --

11:37:15 THE COURT: If that's true, isn't pain that predated filter relevant?

MR. COMBS: -- I'm going to withdraw my objection to that and clarify with Mr. Rogers.

THE COURT: Okay, so we'll be putting in a redacted

11:37:26 exhibit?

MR. ROGERS: Yes, Your Honor.

MS. HELM: Your Honor.

Lincoln and Mark.

On this redaction issue, there are so many redactions

11:37:32 that are going back and forth and we have an agreement to only check the exhibits. We're going to check all the redactions both for the cranial migration and also where we end up on medical records. But I did want you to know that Mr. Clark and I had a conversation about that and we're passing them

11:37:48 back and forth as best we can.

THE COURT: Okay.

MR. COMBS: Everybody's working hard with good faith, Your Honor.

(Bench conference concludes.)

11:37:57 THE COURT: Thank you, ladies and gentlemen.

Exhibit 8067 is admitted.

(Exhibit 8067 admitted.)

BY MR. ROGERS:

Q Doctor, do you have the exhibit?

A I do.

MR. ROGERS: And, Your Honor, could we display the exhibit, please?

THE COURT: Yes.

BY MR. ROGERS:

Q On this particular date, Dr. Hurst, would you agree with me that the chief complaint that is indicated there --

MR. ROGERS: Would you kind of pull that out, please, Scott --

BY MR. ROGERS:

Q -- that the chief complaint that Mrs. Jones complained of on that date was chest pain? Am I correct?

A Yes. She was short of breath, diaphoresis, chest pain, squeezing sensation in the middle of the chest. Yes.

Q And did she describe the chest pain as a 10 on a scale of 10?

A Yes.

Q Doctor --

MR. ROGERS: You can take that down.

BY MR. ROGERS:

Q -- did Mrs. Jones have a chest X-ray as part of that

visit?

A Yes.

MR. ROGERS: And can you pull up Exhibit 7598, please.

Your Honor, I move for admission of this exhibit.

THE COURT: Any objection?

MR. COMBS: Your Honor --

THE COURT: 7598.

MR. COMBS: No objection, Your Honor.

THE COURT: Hold on just a minute.

THE COURTROOM DEPUTY: On my list it shows as a place holder. Is there another number for that? 7958.

THE COURT: Hold on just a minute. We want to make sure that's the right exhibit number.

(Courtroom deputy and counsel confer.)

THE COURTROOM DEPUTY: It just needs added to the list.

THE COURT: All right. 7598 is admitted. I think you said no objection, didn't you, Mr. Combs?

MR. COMBS: No objection.

THE COURT: All right. Admitted.

(Exhibit 7598 admitted.)

MR. ROGERS: Your Honor, may we display this to the jury, please?

THE COURT: You may.

BY MR. ROGERS:

Q Dr. Hurst, do you have the exhibit there in front of you?

A I do.

MR. ROGERS: And, Scott, if you would, could you please pull out the impression down near the lower part.

Thank you.

BY MR. ROGERS:

Q And, Doctor, would you agree with me that the report of the radiologist that read this film was that this was a normal chest X-ray?

A Correct.

MR. ROGERS: And can we pull up Exhibit 8068, please.

Your Honor, I move for admission of Exhibit 8068 into evidence.

MR. COMBS: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 8068 admitted.)

BY MR. ROGERS:

Q Would you pull up number 1 under where it says Discharge Diagnosis, about midway through.

Thank you.

BY MR. ROGERS:

Q And, Doctor, would you agree with me that this is one of the discharge diagnoses that Mrs. Jones received following this hospitalization?

11:41:45 A I agree.
Q Would you agree with me that the diagnosis made by the doctor was chest pain that was noncardiac in origin, likely costochondritis?
11:41:54 A Yes.
Q And can you explain for the jury, please, what costochondritis is.
A Costochondritis is basically an inflammation of the junction between the sternum and the rib. Where it meets
11:42:05 there's what's called the costochondral junction. It's a tissue that can get inflamed. Causes point tenderness over the chest. Can masquerade as a heart attack in some people if it's severe.
MR. ROGERS: And, Your Honor, may I publish this
11:42:22 exhibit?
THE COURT: Yes.
BY MR. ROGERS:
Q And would you agree with me, Doctor, that costochondritis is typically considered to be muscular in nature?
11:42:31 A Musculoskeletal, yeah.
Q And, Doctor, you didn't review any of these actual medical records relating to this hospital admission; correct?
A No. This is prior to the filter placement.
Q Doctor, let's move on to an admission that Mrs. Jones had
11:42:44 in August of 2013. And I believe you didn't review any

11:42:47 medical records related to that admissions either, did you?
A Let me pull up my report here.
What date are you asking for?
Q The date would be August the 14th, 2013.
11:43:14 A No.
Q Okay.
MR. ROGERS: So could we pull up, please, Exhibit 8069.
And, Your Honor, I move for admission of Exhibit 8069 into evidence.
11:43:26 MR. COMBS: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 8069 admitted.)
MR. ROGERS: May I publish the exhibit?
11:43:57 THE COURT: You may.
BY MR. ROGERS:
Q Doctor, on this particular admission in August of 2013, am I right that Ms. Jones' chief complaint was something called syncope?
11:44:08 A Yes.
Q And can you explain to the jury what that is, please.
A So syncope is basically when you get lightheaded and pass out, or near pass out.
Q And did she also complain specifically of lightheadedness in that admission?
11:44:24

11:44:27 A Yes.
Q Doctor, did Ms. Jones receive a chest X-ray as part of that admission?
A Yes.
11:44:32 MR. ROGERS: And could we pull up Exhibit 8070, please.
Your Honor, I move for admission of 8070 into evidence.
MR. COMBS: No objection.
11:44:52 THE COURT: Admitted.
(Exhibit 8070 admitted.)
MR. ROGERS: May we publish?
THE COURT: Yes.
BY MR. ROGERS:
11:44:57 Q And, Dr. Hurst, do you see this Exhibit 8070?
A Yes.
Q And would you agree with me that this is the report from the radiologist who read Ms. Jones' chest X-ray in August of 2013?
11:45:10 A Yes.
Q And, Doctor, if you look down there --
MR. ROGERS: Thank you, Scott. Would you pull up the Impressions section, please.
BY MR. ROGERS:
11:45:16 Q And would you agree with me, Doctor, that the

radiologist's impression was that this was a normal chest exam?

A Correct.

MR. ROGERS: And could we flip back real quick to Exhibit 8069.

BY MR. ROGERS:

Q And, Doctor, down at the bottom of the page there -- well, actually, I don't see.

MR. ROGERS: I'm sorry, would you go to page 7 of that document, please.

And down at the bottom of this page, Scott, would you please pull out the primary diagnosis.

Thank you.

BY MR. ROGERS:

Q And, Doctor, would you agree with me the diagnosis -- or one of the diagnoses that Ms. Jones received on that date was that she was dehydrated?

A Yes.

Q And you didn't look at any of these medical records; correct?

A Not these, no.

Q And in most of the reports from the chest X-rays that we looked at in both 2012 and 2013, would you agree with me that the radiologist did not note anything about a filter in Mrs. Jones' lung?

11:46:25 A Because it wasn't in the lung yet.
Q Okay. So you would agree it had not migrated to the lung at that point?
A Yeah, I would agree.
11:46:32 Q All right. Let's move on to April of 2015.
And, Doctor, would you agree with me that in April of 2015 is when Mrs. Jones went to the ER and it was discovered that she had a fracture of a strut in her lung as an incidental finding?
11:46:52 A What do you mean by incidental finding?
Q Well, Doctor, would you agree with me she did not come into the hospital because she felt like she had a strut in her lung? Is that true?
A Well, I don't think anybody knows they have a strut in
11:47:05 their lungs. Why did she come to the hospital? She came to the hospital because she had arm pain and chest pain.
Q Okay. And Doctor, were you aware -- and the day she did come to the hospital was August the -- excuse me, April the 22nd, 2015; right?
11:47:22 A She came in April 21st first, then came in April 22nd. She came in two days in a row.
Q Okay. So you're aware she went to the ER two days in a row?
A I am.
11:47:33 Q The first admission to the ER, that was not contained in

your report; correct?

A Well, I -- I think it is, but, okay, go ahead.

Q Well, let's take a look at --

A I have those medical records but --

Q Okay, let's take a look at the admission from April 21st, 2015.

A Sure.

MR. ROGERS: Can we pull up 7953.

Doctor, I move -- excuse me. Your Honor, I move for admission of 7953 into evidence.

MR. COMBS: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 7953 admitted.)

MR. ROGERS: May we publish?

THE COURT: Yes.

MR. ROGERS: Scott, would you look at the middle section there where it says under Comment -- it says Chief Complaint on the left and it says Comment.

BY MR. ROGERS:

Q Do you see that part?

A Right.

Q Doctor, would you agree with me that on the 21st of April, 2015, Mrs. Jones came to the ER complaining of being faint and dizzy; is that right?

A Yeah.

11:48:38 Can we hold on just a second? I'd like to pull up these medical records for a second so that I have them completely. You're just showing small portions of the record.

Q Doctor, I'm not going to ask you any more questions about

11:49:19 that exhibit, if you want to move on.

A Well, I think you just have the chief complaint here, you don't have the history and physical that was done that day.

Q Well, that was what she reported as her chief complaint; correct?

11:49:31 A Correct, but that's not the history and physical. So the chief complaint is what the physician synopsizes as her complaint. It may not include all of her symptoms.

Q Well, and you would agree with me that at some point during this admission she also complained of chest pain;

11:49:48 correct?

A She complained of chest and arm pain. Shoulder pain, actually, radiating to her hands.

Q Okay. And let's talk for a moment about her feeling faint and dizzy.

11:49:57 Do you see that?

A Yes.

Q And, Doctor, you're aware that Mrs. Jones is anemic; correct?

A Correct.

11:50:03 Q And you would agree with me that at this point in time she

had had anemia for at least ten years; right?

A Yes.

Q And you also agree anemia can cause a patient to feel faint and dizzy. True?

A Absolutely.

Q And, Doctor, as we have discussed, Mrs. Jones returns to the ER on the following day, on April the 22nd, 2015; correct?

A Yes.

Q And when she came back, were her complaints essentially the same as what she had on the prior day?

A Hold on just a minute.

So from the medical record, she came to the emergency department yesterday with a similar complaint for reasons unspecified. Today she came in with similar complaints that have been ongoing. Lightheadedness was primarily April 21st when she was at work cleaning as a janitor. She states the lightheadedness was accompanied with some diaphoresis. She denies any chest pain, shortness of breath, back pain, abdominal pain, nausea, vomiting, or focal weakness --

THE COURT: Excuse me, Doctor, are you reading from the exhibit?

THE WITNESS: No, I'm not, I'm reading from her medical record.

THE COURT: We shouldn't have you reading in something that's not an exhibit in the trial.

11:51:30 MR. ROGERS: Thank you, Your Honor.

BY MR. ROGERS:

Q I'm going to move on, okay, Dr. Hurst?

A Well --

11:51:34 Q And, Doctor, your counsel will have an opportunity to ask you any questions he wants to on redirect.

A Okay. Fine.

Q And, Doctor, during this admission in April 22nd, 2015, this is when it was discovered that there was a strut in

11:51:47 Mrs. Jones' lung; correct?

A Yes.

Q And you would agree with me that her treating doctors made the determination to try to remove that filter, the Eclipse filter; right?

11:51:59 A Yes, because they felt it was deteriorating.

MR. ROGERS: Can we pull up Exhibit 7951, please.

And I move for admission of Exhibit 7951.

THE COURT: Mr. Combs?

MR. COMBS: No objection, Your Honor.

11:52:23 THE COURT: Admitted.

(Exhibit 7951 admitted.)

MR. ROGERS: May we publish, please, Your Honor?

THE COURT: Yes.

MR. ROGERS: If you'd go to page 2, please, of that

11:52:29 document. And, Scott, if you would, can you pull out that

11:52:32 part where it says "procedure date" right underneath that. Do you see that?

BY MR. ROGERS:

Q And, Doctor, is this a record that would come from the

11:52:41 cath lab --

A Yes.

Q -- where the filter was removed?

A Yes.

Q And when you're doing those type of procedures like

11:52:48 implanting a filter or removing a filter, is everything that's being done in the cath lab at that point being recorded as it's happening?

A Absolutely.

Q And, Doctor, this particular document we're looking at

11:52:59 here, the procedure start time, would that indicate the time that the procedure began?

A Yes.

Q And that says 11:39.

A Yes.

11:53:08 Q And the procedure end time was 12:13; is that right?

A Looks like it went pretty quick.

Q So would you agree the entire process of removal of Mrs. Jones' filter took a little more than 30 minutes?

A Looks like it was uneventful.

11:53:21 Q All right.

11:53:21 MR. ROGERS: Can we go to page 5 of that exhibit, please. And, Scott, if you would, you see where it says 11:58 and it says "right internal jugular accessed." Can you pull up everything through "filter recovery system out."

11:53:43 BY MR. ROGERS:

Q And, Doctor, what we're seeing here, is this that kind of moment-by-moment recording of events in the cath lab?

A This looks like a routine filter removal.

Q Doctor, would you agree with me that the doctor,

11:53:55 Dr. Nelson, who removed this filter gained access to Mrs. Jones' jugular vein at 11:58; is that right?

A Yes.

Q And it looks like the entire filter recovery system was out by 12:05; is that right?

11:54:08 A Absolutely.

Q So this entire procedure of at least when the filter was being removed took a little bit more than five minutes; is that right?

A Looks like it was a routine removal.

11:54:21 Q So you would agree with me that the filter was successfully removed; right?

A Yes.

Q That was after it had been in place for about five years; correct?

11:54:29 A Correct.

11:54:31 Q And would you agree with me that Mrs. Jones never experienced any pulmonary embolism in that five-year period? True?

A Correct.

11:54:39 Q And regarding the strut that was discovered in her lung, you would agree that Mrs. Jones' doctors decided to leave that in place; right?

A Yes.

Q And you don't disagree with that decision, do you?

11:54:53 A No, I don't.

Q And, Doctor, am I correct that you have never had a patient who has had a strut in their lung or pulmonary artery; is that right?

A I have not.

11:55:03 Q So you never managed a patient in that position; correct?

A I have not. Fortunately.

Q And, Doctor, the CT scan that you showed the jury that showed the strut in her lung, do you recall that?

A I do.

11:55:17 Q And I believe you said there were 300 to 400 images from that CT scan?

A Correct, um-hmm.

Q And the CT scan is showing many different slices of Mrs. Jones' body; correct?

11:55:27 A Yes.

11:55:28 Q And of all those images, that is the one that you picked out to bring to the jury today; is that right?
A I had several images picked out. We didn't have time to show them all.
11:55:38 Q Doctor, let me kind of change gears a little bit.
Are you familiar with a medical article that was written by Dr. Scott Trerotola about the management of patients with retained filter fragments?
A Yeah. Give me a second, I have it right here.
11:55:53 Go ahead.
Q Doctor, would you agree with me that that particular article is a reliable article?
A What do you mean by reliable?
Q I'm asking if it's something that is published in the
11:56:06 peer-reviewed medical literature?
A This is a retrospective study.
So there are differing levels of scientific evidence that you can have, from the best evidence, which is prospective randomized trial all the way to a case report.
11:56:22 This is just a little bit above a case report. What they did is retrospectively evaluate a series of cases that had come through their institution. So there is significant bias that can be introduced. And in addition, this report was performed by two radiologists who are -- one radiologist who is involved
11:56:42 in this case.

11:56:44 Q Doctor, let me ask you this: Are you familiar with Scott Trerotola?

A I am.

Q And he's a member of the Society of Interventional

11:56:52 Radiologists?

A He is.

Q Is he considered one of the leading thought leaders about IVC filters in this country?

A He is a key opinion leader, yes.

11:57:00 Q Would you also agree with me that his center at the University of Pennsylvania is one of the leading centers in this country for the retrieval of IVC filters or fragments; is that right?

A Yes.

11:57:12 Q And so would you agree with me that the article that Dr. Trerotola published in the journal called Radiology is a reliable article?

A It describes 65 patients and their attempts at retrieving fragments. Yes.

11:57:29 Q Okay. So, Doctor, I'm going to ask you specifically about some things that are in that article.

MR. ROGERS: And, Scott, could you pull up Exhibit 8602, please.

BY MR. ROGERS:

11:57:41 Q And, Doctor, what is the title of this article?

11:57:45 A Management of Fractured Inferior Vena Cava Filters, outcomes by Fragment Location.

Q And would you agree with me this is published just last year in 2017?

11:57:56 A Yes.

MR. ROGERS: And, Scott, if you would, can you go to page 9, please.

And, Scott, do you see this language that starts like in the first full paragraph? Can you highlight that, please.

11:58:16 BY MR. ROGERS:

Q And, Doctor, I'm going to read a portion of Dr. Trerotola's article to you.

A Sure.

Q And does it read, "Perhaps the least strong argument can

11:58:25 be made for retrieving intrapulmonary fragments" -- and that means within the lungs; right?

A That's what it says, yes.

Q It goes on to say, "To our knowledge, no symptomatic intrapulmonary fragment has been reported." Isn't that

11:58:41 correct?

A That's based on how many cases? Do you know?

Q And, Doctor, would you agree with me this is information that is provided within the medical community and to interventional radiologists such as yourself about how to

11:58:56 manage patients who have got fragments in their lung or other

11:59:00 locations?
A This article describes six fragments that were left behind.
Q And, Doctor, in your report you didn't cite any article
11:59:08 from the medical literature discussing any symptoms from a filter fragment in the pulmonary artery, did you?
A That's because I don't think there are any except for this one describing six fragments.
Q Okay.
11:59:20 MR. ROGERS: You can take that down, Scott.
BY MR. ROGERS:
Q Doctor, as far as that strut that is in Mrs. Jones' lung is concerned, would you agree with me that it has become endothelialized?
11:59:32 A It's partially endothelialized. It's still -- a portion of it is still within the vessel.
Q And does endothelialization mean that tissue has grown around that strut?
A Yes, it does.
11:59:45 THE COURT: We're going to break at this point, Mr. Rogers.
Ladies and gentlemen, we will plan to resume at 1 o'clock. We will excuse you at this time.
(The jury exited the courtroom.)
12:00:38 THE COURT: All right, Counsel, as of now plaintiff

12:01:07 has used 17 hours and 21 minutes, and defendants have used four hours and 58 minutes.

We will plan to see you at 1 o'clock.

MR. ROGERS: Thank you, Your Honor.

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 22nd day of May, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter